

25 September 2010

CPD



Cat M strikes again

Latest clawback could be 'tipping point' **pages 7 and 20**

**CPD
ZONE**

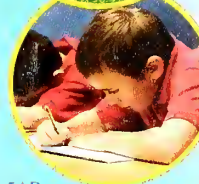
Weighing up the evidence for MS treatments **page 17**

PHARMACIST PRESCRIBING: AVOIDING THE PITFALLS **page 22**

Top tips to boost your skincare sales **page 24**

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NOVARTIS

Legal Category: GSL
 or more information contact the PL holder: Novartis Consumer Health, Horsham, RH12 5AB.
 Source: IRI Chemists including Boots and Superdrug, 52 w/e 21 Mar 2009, Value Sales

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Flomax Relief® MR – Product Information. **Presentation:** Flomax Relief MR containing 0.4mg of tamsulosin hydrochloride in a modified release capsule. **Indication:** Treatment of functional symptoms of benign prostatic hyperplasia (BPH). **Dosage:** For men aged 45-75 years. For oral use. One capsule daily. **Contraindications:** Hypersensitivity to any ingredients of the product; a history of orthostatic hypotension; severe hepatic insufficiency. **Warnings and Precautions:** Men taking an antihypertensive alpha₁-adrenoceptor blocker should consult a doctor before taking Flomax Relief. In individual cases a fall in blood pressure can occur. Do not give to a man who experiences postural hypotension. Consult a doctor before taking Flomax Relief if a man has heart, renal, or liver disease, uncontrolled diabetes, urinary incontinence, or has had prostate surgery. Do not supply Flomax Relief to a man whose symptoms are of less than 3 months' duration. Do not supply to a man who reports dysuria, haematuria, or cloudy urine, in the previous 3 months, or who has a fever that might be related to urinary tract infection. Do not initiate treatment in a man planning cataract surgery, or who has recently experienced blurred or cloudy vision noted by a doctor or optician. If urinary symptoms have not improved within 14 days of starting treatment the patient should be referred to a doctor. Medical review is required for

diagnosis of BPH. Patients must see their doctor within 6 weeks of starting treatment for assessment of their symptoms and confirmation to continue taking Flomax Relief long-term from their pharmacist. Every 12 months, patients should be advised to consult a doctor. **Adverse Effects:** Common: dizziness, Uncommon: headache, palpitations, postural hypotension, rhinitis, constipation, diarrhoea, nausea, vomiting, rash, pruritus, urticaria, abnormal ejaculation, asthenia. Rare: syncope, angioedema. Very rare: priapism. Drowsiness, blurred vision, dry mouth or oedema can occur. IFIS has occurred in some patients during cataract surgery. **RRP (ex VAT):** 14 capsules £7.65, 28 capsules £14.46. **Legal Category:** P. **Product Licence Number:** PL 00015/0280. **Date of revision:** December 2009. **Further information available from:** Boehringer Ingelheim Limited, Consumer Healthcare, Ellesfield Avenue, Bracknell, Berkshire RG12 8YS. **Reference:** 1. Granville G. Racks of make-up and no spanners. Men's Health Forum Report, September 2009.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).



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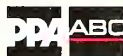
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‘SHOULD THE GOVERNMENT BE REWARDING GPs FOR DEMONSTRATING THEY KNOW HOW TO PLAY THE CONTROL OF ENTRY LOOPHOLES?’

The simmering turf war between primary care's two biggest alpha males is never far from erupting.

And so the news that doctors are increasingly looking to exploit the control of entry exemptions to open their own pharmacies (p6) will do nothing to assuage tensions.

Whatever the arguments are, it ultimately comes down to profits. You can't tell me that a GP would open a pharmacy if they didn't think they'd make a decent return.

There's always been an uneasy truce between the two sides about encroaching over dispensing territories. But with pharmaceutical needs assessments expected to replace control of entry next February, the current trickle of contract applications under the 100-hour exemption will become a stampede as the deadline looms.

And the consequences are just as inevitable: a huge increase in competing pharmacies, a dilution of the global sum, increased costs for the NHS and a poorer service for patients as pharmacists stop investing.

The competition within pharmacy is stiff enough without GPs trying to muscle in on the scene. As our lead story shows (p6), the consequences can be serious. Berkshire pharmacist Jayesh Mistry is facing the very real

prospect of his local surgery opening a 100-hour pharmacy just 100 metres away from his business.

Some will argue that this increases choice and access, but at what cost?

And it's not as if GP-run dispensing practices add value. Where are the advanced and enhanced services, and why do dispensing doctors write more prescriptions than non-dispensing doctors?

As pharmacy lawyer David Reissner highlighted in his column in C+D last month, a high court judge – Dame Janet Smith – has already made her views on dispensing doctors abundantly clear in her Shipman Inquiry report: pharmacists should provide pharmaceutical services independent of the prescribing doctor.

Aside from the threat to the pharmacy network, there is a bigger question for society here. Should the government really be rewarding GPs for demonstrating they know how to play the control of entry loopholes, or should they be paid for helping the unstable long-term unwell stay out of expensive hospitals?

Perhaps it'll take a surge in pharmacies applying for medical contracts before GPs realise the error of their ways.

Gary Paragpuri, Editor

CPD Zone

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Doctors' pharmacy contracts 'could destabilise the sector'

PSNC investigating exploitation of market entry exemptions by GP surgeries

Hannah Flynn

hannah.flynn@ubm.com

Doctors exploiting exemptions for 100-hour and remote pharmacy contracts to open their own dispensaries could destabilise the community pharmacy network, experts have warned.

Contractors also expressed concerns that the moves could lead to prescriptions being directed towards the GP-owned pharmacies. And they said patients would not get the level of service they should from remote pharmacies, as they offer no enhanced services.

PSNC confirmed it was investigating the matter, using freedom of information legislation to determine whether there had been a rise in contract applications from GPs. There are concerns a surge in applications could be seen before legislation makes pharmaceutical needs assessments (PNAs) the basis for pharmacy market entry.

Tony Mottram, Numark's managing director, said: "The current roles of GPs and pharmacists are clear: GPs should diagnose and prescribe and pharmacists should dispense – otherwise there is potential for conflict of interest." And he warned an upsurge in GP applications could upset the stability of pharmacy.

One contractor told C+D: "We are

Berkshire contractor 'gutted' by surgery's 100-hour contract

A 100-hour pharmacy licence has been granted to a dispensing GP surgery in Berkshire, despite a campaign by local villagers who collected 4,000 signatures opposing the move.

The new pharmacy will be just 100 metres away from Jats Pharmacy, which has served the village of Finchampstead for 15 years.

Pharmacist Jayesh Mistry of Jats Pharmacy told C+D: "I am gutted.

For them it is a quick buck, for me it is my income. The staff are wondering what will happen."

He said he was pleased with the response from his customers though. He said: "The patients have been brilliant and the parish council and local council are supporting us. Even some of [the surgery's] patients decided they didn't want the pharmacy at the surgery."

A spokesperson from NHS Berkshire West said: "There are a clear set of NHS regulations that the PCT has to work to in order to determine whether an application should be approved. We do not have any authority to refuse an application that is in line with these rules."

A spokesperson from Finchampstead Surgery said: "Currently no decision has been made as to whether the surgery will proceed further and open a 100-hour pharmacy."



Jayesh Mistry and staff fear for their livelihoods, despite "brilliant" local support

The Wokingham Times

seeing many more GPs jealously eyeing the potential to open their own pharmacies." He warned this could give doctors an incentive to "churn out more and more prescriptions". "What we need is for the pharmaceutical needs

assessments to be done pretty quickly," he added.

PSNC echoed the concerns about an increase in the number of applications from GPs entering the market. Head of Regulation Steve Lutener said: "We have been

pressing for a moratorium on the 100-hour application exemption; however the Department of Health has said you can't have a moratorium without consultation, and if you do that you will stimulate applications."

Letter of advice issued in first CPD breach case

The first pharmacist to be brought before the RPSGB Investigatory Committee for breaching CPD standards has been issued with a letter of advice, according to a Society spokesperson.

The RPSGB has declined to name the pharmacist because of confidentiality concerns, and would not release further hearing details.

The unnamed pharmacist was one of five referred to the Investigating Committee after falling foul of the Society's mandatory CPD checks under the call and review system.

The committee can also refer cases for more serious consideration via the disciplinary or health committees or dismiss them with no further action.

The verdict came as pharmacy regulator the General Pharmaceutical Council (GPhC) agreed a consultation draft of its CPD framework. **HF**

Read the latest IT news, views and FAQs

www.chemistanddruggist.co.uk/ITzone

Tesco first supermarket to supply Viagra without scripts

Tesco has announced it will be the first supermarket to sell Viagra without the need for a prescription.

The move follows a similar Boots service, with both groups providing the drug under private patient group directions (PGD).

Independent pharmacy group Numark backed pharmacists supplying the drug to help safeguard patients, but warned the move could widen the gap between independents and multiples.

Viagra will be available from Tesco to men aged between 40 and 65 years old. Pharmacists will receive a

training package and will have to ask patients to complete a questionnaire, a diabetes screen and blood pressure and cholesterol tests before they supply the drug.

The tablets will be on sale at 300 Tesco stores across the UK from September 27, priced at £52 for eight tablets.

Raj Nutan, director of commercial operations at Numark, said: "It is frustrating that many independents feel that the private PGD route is unavailable to them as it is time-consuming and often not cost effective for a single owner." **SP**



Cat M clawbacks 'too big' for smaller businesses

Loss from purchase profits could be "tipping point" for pharmacies

Zoe Smeaton

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The latest category M clawbacks could be too much for some smaller pharmacies to cope with, industry leaders have warned.

The comments came after multiples said they would need to cut spending following the £140 million clawback. The cuts will see pharmacies losing on average £2,400 from purchase profits next quarter.

But some pharmacies are already struggling with cash flow so the latest clawback "couldn't have come at a worse time", according to Umesh Modi, specialist pharmacy financial adviser at Silver Levene.

Mr Modi said he was advising clients to be careful with investment plans and taking on extra staff. "In a recent case, one of my clients is refinancing his loan and we have had to ask for additional [money] to cover the category M shortfall," he added.

Andy Harwood, director of business development at Pharmacy Partners, agreed some businesses were facing difficulties. He said



margins were now at around 27 to 30 per cent whereas in previous years they had been 33 to 35 per cent. "Rents have been going up and bottom lines are already squeezed – it's one thing after another," he said.

Mark Griffiths, chairman of pharmacy support group Cambrian Alliance, said the clawback could be the "tipping point" for pharmacists already scratching around for their margins. And Mr Modi warned: "On top of the white paper proposals,

removal of some services by the PCTs, the austerity measures and its unknown impact on the economy, this announcement will undermine confidence in this industry."

The NPA called for pharmacists to be able to make reasonable predictions about income and cash flow. Raj Nutan, Numark's director of commercial services, said the money being clawed back should be used to fund pharmacy-led services.

• **Category M Barometer: p20**

Lambeth seeks review of RP impact

The RPSGB Council is set to ask the Department of Health for an appraisal of the impact of the responsible pharmacist regulations.

In a paper submitted to Council this week, RPSGB chief executive Helen Gordon said Society officers believed the review was important "to ensure all issues were dealt with before the new supervision requirements were implemented".

When the responsible pharmacist legislation was introduced last October, RPSGB Council members agreed to report back on how it was being implemented.

Council also discussed the RPSGB's responses to the DH's consultation on its white paper Liberating the NHS and to a consultation on the future of fitness to practise adjudication for health professionals. ZS



Community pharmacy is gearing up this week to provide flu jabs across the UK. Lloyd's pharmacy has offered businesses 10 per cent discount vouchers that can be redeemed by employees, bringing the cost down to £9. The multiple has over 200 participating stores and is also offering to vaccinate employees on site. AAH said its flu vaccination service, delivered under a private PGD, was this year being offered by 350 pharmacists. And Boots announced its flu vaccination service would this year cost £12.99 and be offered from around 300 stores. Pictured is a Lloyd's pharmacy employee receiving her jab from pharmacist Nitin Makadia. ZS

In brief

PCT INVESTIGATION

Find out which PCTs have no pharmacy enhanced services at all. We lift the lid on PCT commissioning at the C+D Senate Live on October 10 at the Pharmacy Show at the Birmingham NEC. Get your free ticket at www.chemistanddruggist.co.uk/the-pharmacy-show.

Teva announce bursary

Generics manufacturer Teva UK has announced its student bursary scheme will run for the third year. It is open to students aiming to complete a pharmacy degree or similar, but who would suffer financial hardship without support. The closing date for applications is October 15.

Security questionnaire

An online questionnaire for pharmacies has been developed by NHS Wales in conjunction with RPSGB Wales, to enable pharmacies to show their compliance with information governance and IT security obligations.

Specials prices

PSNC chief executive Sue Sharpe appeared on BBC Radio 5 Live this week, responding to an investigation that highlighted the high prices some contractors are paying for specials.

www.chemistanddruggist.co.uk

Easier Yellow Card

The MHRA is working with the UK Medicines Information service to make Yellow Card reporting of adverse drug reactions easier for pharmacists. Pharmacists at five UK hospitals are now involved in evaluating the new system, which enables electronic reporting of adverse drug reactions.

IT Zone winner

Congratulations go to S Mistry, of Mistrys Pharmacy in Market Harborough, who wins an iPod Touch after taking part in the IT Zone Survey.



Dispensary talk

How would you solve the Cat M conundrum?

"The current system isn't ideal as it makes it difficult for pharmacies to invest in pharmacy services."

Michael Maguire, Marton Pharmacy, Middlesbrough



"Category M can't be tweaked; it needs to be scrapped. Pharmacies should be paid professionally and properly based on a framework that remunerates outcome not output."

Graham Phillips, Manor Pharmacy (Wheathampstead) Ltd, Hertfordshire



Web verdict

Scrap and replace with central generic tendering 48%

Keep but reinvest in enhanced services 35%

We're stuck with it 17%

Keep it, there are good times and bad 0%

Armchair view: It's a dismal result for Cat M as no one thinks it brings good times, although some think life would be better if the money were returned to pharmacy.

Next week's question:

Are pharmacists the best people to talk to men about Viagra?

www.chemistanddruggist.co.uk

GPhC announces fee structure for 2011

Renewal fees will be £262 for pharmacists and £142 for technicians

Ben Jones

The General Pharmaceutical Council (GPhC) has agreed its fees for 2011 as it prepares to take over pharmacy regulation from September 27.

The annual renewal fees will be £262 for pharmacists, £142 for pharmacy technicians and £217 for pharmacy premises, after these rates were rubber-stamped at a meeting of the Council last week.

The cost for membership of the professional leadership body (PLB) will be £192 and some pharmacists expressed concern at the combined costs, but the GPhC said it could not

base its fees on the PLB's charges.

The regulator has also opted not to offer a low-income fee, despite 55 per cent of respondents to a consultation on the issue saying they felt it should.

"Regulatory responsibility applies to all registrants, whether they work full or part-time and whatever their total income," the Council said.

Readers posting on C+D's website said it "didn't add up" to charge technicians different fees and more than they had been previously charged. But the Council said it would keep the charge under review

as it gained more information about the cost of regulating technicians.

Those who pay their renewal fees by direct debit quarterly instalments will be charged an additional £15, to cover the costs associated with "payment in arrears, technical and operational costs", despite opposition from more than 80 per cent of respondents to the consultation.

Applications to register with the GPhC will have to be made within eight calendar years of starting an MPharm degree or within two years of passing a registration assessment, whichever is sooner.

Clinical debate C+D's Jennifer Richardson looks at the evidence behind the headlines

Not all evidence is created equal



As a science undergraduate, I was often told by arts peers that my subject was easier than theirs because "it was either right or wrong". Last week's reigniting of the glucosamine debate by a BMJ paper has made my counterargument – that there are varying degrees of right – more eloquently than I ever could.

Wandel et al conducted a meta-analysis of 10 trials, concluding that "compared with placebo,

glucosamine, chondroitin, and their combination do not reduce joint pain or have an impact on narrowing of joint space" in osteoarthritis.

But the paper also raises wider issues, including whether pharmacists should sell only evidence-based products. This view has been iterated frequently of late, by both pharmacists and doctors.

It's hard to disagree, in theory. The above researchers added the caveat that they could "see no harm" in patients continuing glucosamine use. But is "no harm" good enough for healthcare professionals to be encouraging, or allowing without intervention, patients to pay for treatments that don't work?

But the real problem is defining what constitutes an evidence base. While 2008 Nice guidelines do not recommend glucosamine as cost-effective for the NHS, some studies have found evidence of effectiveness. An Arthritis Research

UK review last year found the majority of trials of glucosamine sulphate demonstrated significant clinical benefits compared to placebo or NSAIDs, and the charity has pointed out that the large US GAIT trial could be interpreted almost any way you like.

Of course, there are many instances where an overwhelming weight of evidence comes down firmly on one side of the fence. But you only have to look at C+D readers' recent picking apart of results presented as against homeopathy to see that these things are rarely cut and dried.

There may be those who would say homeopathy is in a different ball park to glucosamine – but that only shows how difficult it is to draw the line between the varying degrees of right.

Discuss with Jennifer on Twitter:
www.twitter.com/CandJennifer

**General
Pharmaceutical
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FROM
27
SEPTEMBER

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Dr Brief

Legal conference

The Charles Russell pharmacy team is hosting a conference to help pharmacists get to grips with complex legal and regulatory issues. The conference will be held at Birmingham's International Convention Centre on October 19. To reserve your free place, call 020 7203 5065.

NCSO update

The Department of Health and National Assembly for Wales have agreed to allow NCSO endorsements for the following items for September prescriptions: docusate 100mg capsules, indoramin 25mg tablets, hydrocortisone 2.5mg oromucosal tablets, and gabapentin 400mg capsules.

NPA politics course

NPA members have attended a crash course in local government to help them prepare for changes facing the sector. Stephen Fishwick, NPA head of external communications, said: "Local authorities are to have a more central place in health service commissioning under proposals in the NHS white paper."

Diabetes risk tool

A free diabetes risk pack that determines a person's risk of developing type 2 diabetes is now available for health professionals. The Diabetes Risk Score can help assess patients such as those who do not fall within the NHS Health Check age range. To order a pack visit www.diabetes.org.uk.

DH pledge to lift RP restriction 'not enough'

DH explanation for EU responsible pharmacist rule is 'a fudge'



French locum Dr Fosso Taga claimed UK law was discriminatory

Hannah Flynn
hannah.flynn@ubm.com

A Department of Health (DH) letter to the European Commission (EC) confirming it will remove the restriction on EU-qualified pharmacists being responsible for new pharmacies, is "a fudge" and not satisfactory, experts have said.

The DH said ministers were minded to remove the restriction, but it did not offer a date for the change, warning the timetable was subject to consultation and to Parliamentary process.

The DH letter was a written response to an EC query that came after a complaint by French locum Dr Fosso Taga. Dr Taga claimed UK law preventing EU-qualified pharmacists being responsible for

pharmacies registered less than three years was discriminatory.

The DH said the decision to change the law was not linked to the complaints raised by Dr Taga and it defended the principle of the restriction.

But David Reissner, head of healthcare at law firm Charles Russell, called the department's statement a fudge. "There is no genuine justification for the three-year rule and if the case were to go forward to the European Court, it is difficult to see how it would be upheld," he said.

Dr Taga said he too was not satisfied with the DH's response as he wanted a date for the change. He said: "There is no date, which is exactly what they told me in 2007 when I made the initial complaint."

MUR quality concerns

Concerns about the quality of MURs have been raised again following a report for the National Institute for Health Research Service Delivery and Organisation Programme.

Pharmacists who took part in the study said they felt under pressure from employers to deliver target volumes of MURs. And the research identified reluctance from doctors as a key barrier to the reviews.

The results echoed previous concerns about MURs, and the majority of GPs involved said MURs were a waste of time and money.

Mike Holden, chief officer of Hampshire and Isle of Wight LPC, called for more evaluation of MURs. He said: "We need GPs and pharmacists working together to agree a target audience and gain an understanding of what the MUR is and the benefits it holds."

Stephen Fishwick, head of external communications at the NPA, said the association was working with the Primary Care Pharmacists Association to help devise guidance on effective written communication with GPs. **SP**

Patients first

Pharmacists are prepared to break professional guidelines in the interests of patient safety, a report published by the Pharmacy Practice Research Trust has said.

Pharmacists rated patients' health interests as the most important factor in ethical decision making.

University of Nottingham professor of pharmacy law and ethics Joy Wingfield said: "It is heartening that the 'common sense' ethical values embedded in pharmacy practice ensure that patients' interests remain paramount." **AB**



Sci-MX nutrition range sports new look and gets £1m support



Sci-MX's sports nutrition product range is being repackaged, the company has announced.

The brand will also be the focus of a £1 million promotional spend, including consumer advertising and PR, in the second half of 2010.

Independent research has shown that many people are put off purchasing sports nutrition products as they find the category confusing.

The redesigned Sci-MX packaging will address that issue for customers,

Market focus

- The global sports nutrition market has been predicted to reach \$91.8 billion by 2013, growing at 24 per cent.

- The sports supplements subcategory has been predicted to reach \$2.5bn in the same timeframe, growing at 10 per cent.

Source: BCC Research

according to the company.

Prices and Pip codes: See C+D Monthly Price List or
www.cddata.co.uk
Sci-MX
Tel: 01452 656010

Dove tackles hair damage

Unilever UK has announced the launch of haircare range Dove Damage Therapy.

The launch is supported by a £3.2 million marketing spend, which includes television advertising and an investment in nationwide shopping centre sampling campaigns aimed at driving trial and purchase.

The products use patented technologies Fibre Active Technology and Micro Moisture Serum, the company says, to combat damage to hair caused by daily care and styling.

The range comprises 18 products, including two Express Treatment Conditioners that Unilever says "are what set this range apart from competitors".

Prices and Pip codes: See C+D Monthly Price List or
www.cddata.co.uk
Unilever UK
www.unilever.co.uk

Strepsils lozenge gets warmer

Reckitt Benckiser has launched Strepsils Warm Lozenges, as it unveiled its "biggest ever pharmacy support plan" for the brand.

And the manufacturer will this winter be spending more than £4 million on a multimedia marketing campaign for Strepsils, which it says will reach 80 per cent of pharmacy customers, as well as revealing new packaging.

The new product is the first warming sensation sore throat lozenge, according to Reckitt Benckiser, developed in response to customer research.

Also in response to customer feedback, the company is bringing

back the pharmacy-only 24-tablet pack for the brand's two most popular sellers – Strepsils Honey & Lemon and Strepsils Extra Strength Blackcurrant – as part of a pharmacy-exclusive range.

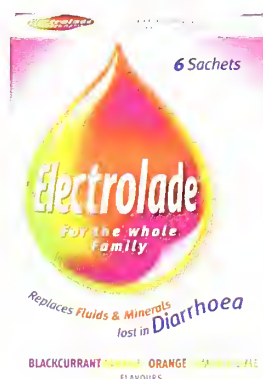
A new-look website is being developed, with a section on pharmacy-only products. These will also be supported by online advertising, Reckitt Benckiser says, and pharmacy-only PoS material.

Prices and Pip codes: See C+D Monthly Price List or
www.cddata.co.uk
Reckitt Benckiser
www.rb.com

New pack for Electrolade

Actavis has announced the repackaging of its rehydration brand, Electrolade.

The pack now features a droplet



design to reflect the product's rehydrating properties, according to the company.

Actavis found the design was positively received by consumers, with 94 per cent finding the new packaging very appealing and 96 per cent saying they prefer the new design over the old one.

Electrolade is available in six and 20-sachet packs in a variety of flavours.

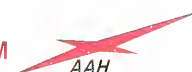
Prices: £2.35/6; £7.99/20
Pip codes: See C+D Monthly Price List or www.cddata.co.uk
Actavis
Tel: 0800 373573

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EADY

CONNECTING YOU TO A BETTER FUTURE Pro

LINK ONLY FROM



Letters

The worst natural calamity in Pakistan's history



diarrhoea and dysentery, especially in children who are already weak and vulnerable. Health problems usually arise in flood-affected areas after four to six weeks and this problem needs to be tackled with immediate effect.

We need to provide the basic supplies and equipment to these communities and I am requesting fellow pharmacists to provide support by either donating to www.dec.org.uk or, if living in the Greater Manchester area, people can construct food parcels. These will be flown out, courtesy of Pakistan International Airlines, and delivered directly into the hands of the Red Cross in Pakistan, which will then deliver and distribute them to the hardest hit areas affected by the floods by helicopter with the help of Pakistan army within 48 hours.

I am calling on all healthcare professionals and businesses – let's work together and use our resources to help make our world a better and safer place to live in.

Khalid Ahmed, pharmacy manager, Asda Pharmacy, Manchester

The events in Pakistan have been described by the UN general secretary Ban Ki-moon as a 'slow motion tsunami' and I believe it is the world's biggest natural disaster.

Villages have been displaced, families have been left watching the disaster unfold in front of their eyes leaving total devastation and destruction. More than 17 million people have been affected by the floods, with about 1.2 million homes destroyed.

Pakistan's Prime Minister Yousuf Raza Gilani says the government is "seriously concerned" about the potential spread of epidemic diseases in the flood-hit country.

There is likelihood of water-borne diseases such as cholera,

Contact us

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Or write to the Editor at: **C+D, Ludgate House, 245 Blackfriars Road, London SE1 9UY.** Letters may be edited for content and length

Duncan Rudkin: Life under the new pharmacy regulator



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Presentations: Advagraf® Prolonged-release hard capsules containing tacrolimus 0.5 mg, 1 mg, 3mg and 5 mg Prograf® hard capsules containing tacrolimus 0.5 mg, 1 mg and 5 mg. **Indications:** Advagraf and Prograf: Prophylaxis of transplant rejection in adult liver or kidney allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products. **Dosage and Administration:** Advagraf and Prograf therapy require careful monitoring by adequately qualified and equipped personnel. Either drug should only be prescribed, and changes in immunosuppressive therapy initiated, by physicians experienced in immunosuppressive therapy and the management of transplant patients. Dosage recommendations given below should be used as a guideline. Advagraf or Prograf are routinely administered in conjunction with other immunosuppressive agents in the initial post-operative period. The dose may vary depending on the immunosuppressive regimen chosen. Dosing should be based on clinical assessments of rejection and tolerability aided by blood level monitoring. To suppress graft rejection immunosuppression must be maintained so no limit to the duration of oral therapy can be given. The daily dose of Advagraf capsules should be taken once daily in the morning with water at least 1 hour before or 2-3 hours after a meal. Prograf capsules should be taken as for Advagraf in two divided doses. Advagraf: In stable patients converted from Prograf (twice daily) to Advagraf (once daily) on a 1:1 (mg/mg) total daily dose basis the systemic exposure to tacrolimus for Advagraf was approximately 10% lower than for Prograf. The relationship between tacrolimus trough levels (C_{0-1}) and systemic exposure (AUC_{0-12}) for Advagraf is similar to that of Prograf. When converting from Prograf capsules to Advagraf trough levels should be measured before and within two weeks after conversion. In de novo kidney and liver transplant patients AUC_{0-12} of tacrolimus for Advagraf on Day 1 was 30% and 50% lower respectively, when compared with that for Prograf at equivalent doses. By Day 4, systemic exposure as measured by trough levels is similar for both kidney and liver transplant patients with both formulations. **Race:** In comparison to Caucasians, Afro-Caribbean patients may require higher tacrolimus doses to achieve similar trough levels. **Prophylaxis of transplant rejection – liver and kidney:** Initial dose of Advagraf and Prograf capsules is 0.10-0.20 mg/kg/day for liver transplantation and 0.20-0.30 mg/kg/day for kidney transplantation starting approximately 12-18 hours for Advagraf and 12hrs for Prograf after completion of liver or within 24 hours of completion of kidney transplant surgery. **Dose adjustment post-transplant:** Advagraf and Prograf doses are usually reduced in the post-transplant period. It is possible in some cases to withdraw concomitant immunosuppressive therapy leading to Advagraf monotherapy or Prograf dual therapy or monotherapy. Post-transplant improvement in the condition of the patient may alter the pharmacokinetics of tacrolimus and may necessitate further dose adjustments. **Dose recommendations – Conversion to Advagraf:** Patients maintained on twice daily Prograf requiring conversion to once daily Advagraf should be converted on a 1:1 (mg/mg) total daily dose basis. Following conversion, tacrolimus trough levels should be monitored and if necessary dose adjustments made. Care should be taken when converting patients from ciclosporin-based to tacrolimus-based therapy. Initiate Advagraf after considering ciclosporin blood concentrations and clinical condition of patient. Daily dosing in presence of elevated ciclosporin blood levels. Monitor ciclosporin blood levels following conversion. **Dose recommendations – Rejection therapy:** For conversion of kidney and liver recipients from other immunosuppressants to once daily Advagraf, begin with the respective initial dose recommended for rejection prophylaxis. In adult heart transplant recipients converted to Advagraf, an initial oral dose of 0.15 mg/kg/day should be administered once daily in the morning. For other allografts, see SPC. **Dose adjustments in specific populations:** See SPC. **Trough whole blood trough concentration recommendations:** Blood trough levels for Advagraf should be drawn approximately 24 hours post-dosing, just prior to the next dose, for Prograf approximately 12 hours post-dosing. Frequent trough level monitoring in the first two weeks post-transplant is recommended, with periodic monitoring during maintenance therapy. Monitoring is also recommended following conversion from Prograf to Advagraf, dose adjustment, changes in the immunosuppressive regimen, or co-administration of substances which may alter tacrolimus whole blood concentrations (see 'Warnings and Precautions' and 'Interactions'). Adjustments to the Advagraf and Prograf dose regimen may take several days before steady state is achieved. Most patients can be managed successfully if tacrolimus blood concentrations are maintained below 20 ng/mL. In clinical practice, whole blood trough levels have been 5-20 ng/mL in liver transplant recipients and 10-20 ng/mL in kidney transplant recipients early post-transplant, and 5-15 ng/mL during maintenance therapy. **Contraindications:** Hypersensitivity to tacrolimus or other macrolides or any excipient. **Warnings and Precautions:** Medication errors, including inadvertent, unintentional or unsupervised substitution of immediate or prolonged-release tacrolimus formulations, have been observed. This has led to serious adverse events, including graft rejection, or other side effects which could be a consequence of either under- or over-exposure to tacrolimus. Patients should be maintained on a single formulation of tacrolimus with the corresponding daily dosing regimen; alterations in formulation or regimen should only take place under the close supervision of a transplant specialist. Advagraf: only limited experience in non-Caucasian patients and those at elevated immunological risk. Advagraf is not recommended for use in children below 18 years due to limited data on safety and efficacy. Advagraf and Prograf: During initial period routinely monitor blood pressure, ECG, neurological and visual status, fasting blood glucose, electrolytes (particularly potassium), liver and renal function tests, haematology parameters, coagulation values, and plasma protein determinations; consider adjusting the immunosuppressive regimen if clinically relevant changes are seen. Herbal preparations, including those containing St. John's Wort, should be avoided. Extra monitoring of tacrolimus concentrations is recommended during episodes of diarrhoea. Avoid concomitant administration of ciclosporin. Ventricular hypertrophy or hypertrophy of the septum (reported as cardiomyopathy) have been seen rarely, other

risk factors for these conditions include pre-existing heart disease, corticosteroid usage, hypertension, renal or hepatic dysfunction, infections, fluid overload, and oedema. Patients are at increased risk of all opportunistic infections including BK Virus associated nephropathy and JC Virus associated progressive multifocal leukoencephalopathy. Physicians should consider this in their differential diagnosis in immunosuppressed patients with deteriorating renal function or neurological symptoms. Patients have been reported to develop posterior reversible encephalopathy syndrome (PRES). If so radiological tests should be performed. If PRES is diagnosed, adequate blood pressure and seizure control and immediate discontinuation of tacrolimus is advised. Echocardiography or ECG monitoring pre- and post-transplant is advised in high-risk patients, and dose reduction of and/or a change of immunosuppressive agent should be considered if abnormalities develop. Tacrolimus may prolong the QT interval. Exercise caution in patients with diagnosed or suspected Congenital Long QT Syndrome. EBV-associated lymphoproliferative disorders have been reported. Concomitant use of other immunosuppressives such as antilymphocytic antibodies increases the risk of EBV associated lymphoproliferative disorders. EBV-VCA negative patients have been reported to have increased risk of lymphoproliferative disorders; EBV-VCA serology should be ascertained before starting tacrolimus treatment. During treatment, careful monitoring with EBV-PCR is recommended. Exposure to sunlight and UV light should be limited. The risk of secondary cancer is unknown. Dose reduction may be necessary in patients with severe liver impairment. The pinking ink used to mark Advagraf capsules contains soya lecithin. In patients who are hypersensitive to peanut or soya, the risk and severity of hypersensitivity should be weighed against the benefit of using Advagraf. Capsules contain lactose. **Interactions:** See SPC. **Pregnancy and lactation:** Tacrolimus can be considered in pregnant women when there is no safer alternative. See SPC. **Undesirable effects:** Medication errors have been observed. A number of associated cases of transplant rejection have been reported (frequency cannot be estimated from the available data). Many of the following adverse drug reactions are reversible and/or respond to dose reduction. **Very Common (>1/10):** Hyperglycaemic conditions, diabetes mellitus, hyperkalaemia, insomnia, tremor, headache, hypertension, diarrhoea, nausea, renal impairment, infections, liver function test abnormal, Common (>1/100 to <1/10): haematological abnormalities, hypomagnesaemia, hypophosphataemia, hypokalaemia, hypocalcaemia, hyponatremia, fluid overload, hyperuricaemia, appetite decreased, anorexia, metabolic acidosis, hyperlipidaemia, hypercholesterolaemia, hypertriglyceridaemia, anxiety symptoms, mental disorders, confusion and disorientation, depression, mood disorders and disturbances, nightmares, hallucinations, seizures, disturbances in consciousness, paraesthesiae and dysesthesias, peripheral neuropathies, dizziness, writing impaired, vision blurred, photophobia, eye disorders, tinnitus, ischaemic coronary artery disorders, tachycardia, haemorrhage, thromboembolic and ischaemic events, vascular hypotensive disorders, peripheral vascular disorders, dyspnoea, parenchymal lung disorders, pleural effusion, pharyngitis, cough, nasal congestion and inflammation, gastrointestinal inflammatory conditions, gastrointestinal ulceration and perforation, gastrointestinal haemorrhages, stomatitis, ascites, vomiting, gastrointestinal and abdominal pains, constipation, flatulence, bloating and distension, loose stools, bile duct disorders, hepatic enzymes and function abnormalities, cholestasis and jaundice, hepatocellular damage and hepatitis, cholangitis, pruritus, rash, alopecia, acne, sweating increased, arthralgia, muscle cramps, limb and back pain, renal failure, oliguria, renal tubular necrosis, nephropathy toxic, bladder and urethral symptoms, asthenic conditions, febrile disorders, oedema, blood alkaline phosphatase increased, weight increased, body temperature perception disturbed, primary graft dysfunction. **Uncommon (>1/1000 to <1/100):** coagulopathies, coagulation and bleeding analyses abnormal, pancytopenia, hypoproteinaemia, hyperphosphataemia, hypocalcaemia, coma, central nervous system haemorrhages and cerebrovascular accidents, paralysis and paresis, encephalopathy, speech and language disorders, amnesia, cataract, arrhythmias, cardiac arrest, heart failures, cardiomyopathies, infarction, deep venous thrombosis, shock, respiratory failures, respiratory tract disorders, asthma, paralytic ileus, peritonitis, acute and chronic pancreatitis, anuria, haemolytic uraemic syndrome, uterine bleeding, pancytopenia, multi-organ failure. **Rare (>1/10,000 to <1/1000):** thrombotic thrombocytopenic purpura, blindness, sensory deafness, pericardial effusion, acute respiratory distress syndrome, subileus, pancreatic pseudocyst, hepatic artery thrombosis, venocclusive liver disease, toxic epidermal necrolysis (Lyell's syndrome). **Very rare (<1/10,000 including isolated reports):** hepatic failure, Stevens Johnson syndrome, nephropathy, cystitis haemorrhagic, Neoplasms. Consult the SPC for complete information on side effects and full prescribing information. **Package Quantities, Basic NHS cost & Product licence numbers:** Advagraf/Prograf 0.5 mg capsules x 50 = £35.79 (EU/1/07/387/002)/£61.88 (PL 00166/0206), respectively. 1 mg capsules x 50 = £71.59 (EU/1/07/387/004)/£80.28 (PL 00166/0203), respectively. 1 mg capsules x 100 = £143.17 (EU/1/07/387/006)/£160.54 (PL 00166/0203), respectively. 5 mg capsules x 50 = £266.92 (EU/1/07/387/008)/£296.58 (PL 00166/0204), respectively. Advagraf 3 mg capsules x 50 = £214.76 (EU/1/07/387/012). **Legal Classification:** POM. **Date of Revision:** May 2010. Further information available from Astellas Pharma Ltd, Lovett House, Lovett Road, Staines TW18 3AZ. Advagraf and Prograf are registered trade marks. For medical information phone 0800 783 5018

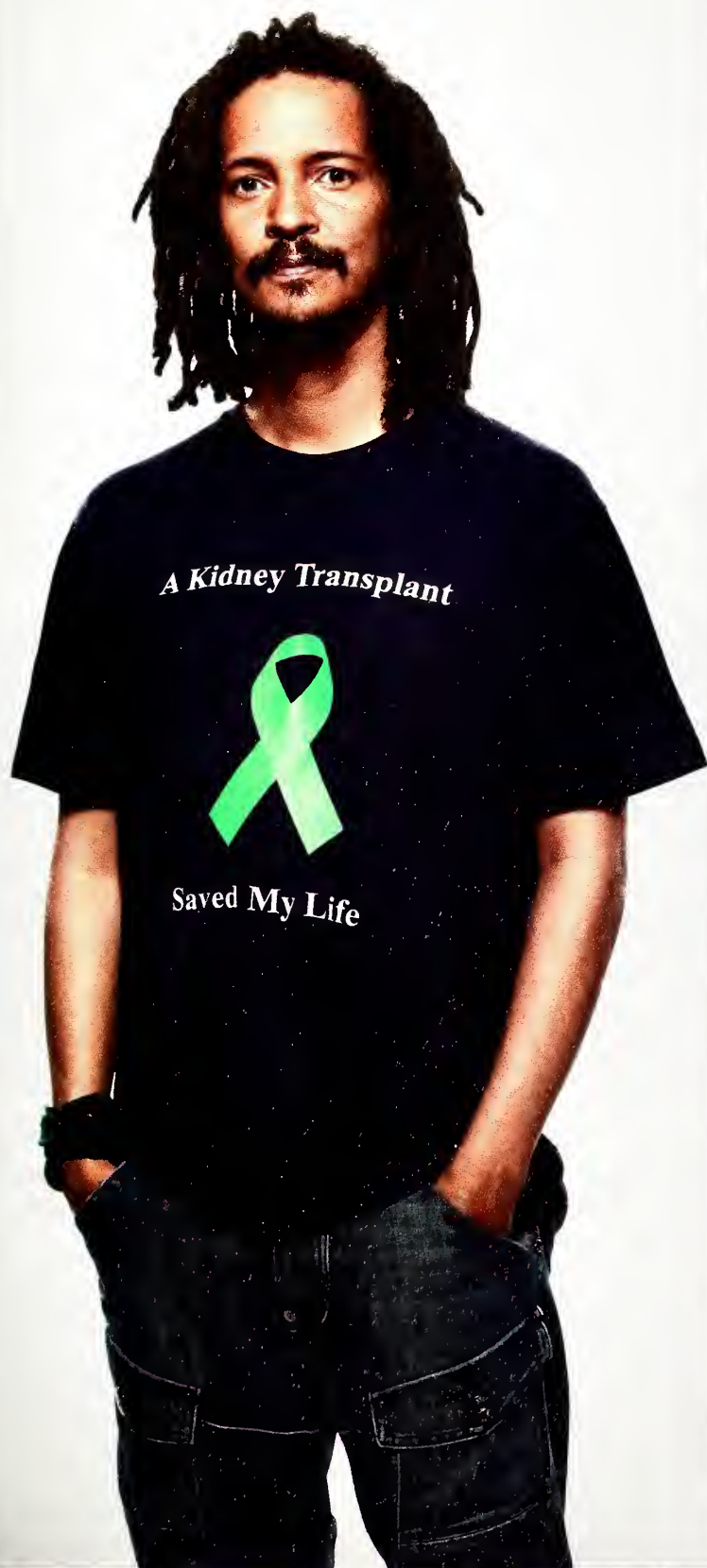
Adverse events should be reported.
Reporting forms and information can be found at www.yellowcard.gov.uk.
Adverse events should also be reported to
Astellas Pharma Ltd – 0800 783 5018

References

- * NHS Blood and Transplant, August 2009: NHS Transplant Activity in the UK, 2008-2009.
- † www.kidney.org.uk June 2010.

Job code: PRG10028UK Date of preparation, June 2010





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Defending the indefensible?

Pharmacist and Alliance Healthcare chairman Mike Smith is passionate about pharmacy. But if the sector doesn't wake up to the threat of pharmaceutical needs assessments or deals with the supply chain mess, there could be trouble ahead

It has been my privilege to sit on NHSAA litigation authority appeal panels for more than 20 years.

As one of those who fought for control of entry over 20 years ago, I fear that the regulations may come back and bite us on the bum.

I became involved in the first place because two separate attempts were made to 'leap-frog' my pharmacies in Devon, which could have wiped me out, so I well understand the passion of those who defend the status quo.

We invest heavily in our pharmacies for diminishing returns and the least we can expect is reasonable future security, but we have to be good enough to enjoy this privilege, and it is a privilege.

But there is a caveat.

The fact is that there are those pharmacists who do not sit up and take notice when it comes to improving premises and providing services etc until they are faced with an application for a new contract in their neighbourhood.

I should emphasise that this applies to all sectors – both independents and multiples – and demonstrates an inherent weakness in our profession.

We read more frequently now that control of entry may disappear. Just think, 100-hour pharmacies would become 40-hour pharmacies and leap-frogging would return with a vengeance.

The PCTs are charged with the preparation of pharmaceutical needs assessments (PNA) by February 2011. PCTs will be abolished in 2013 and community pharmacy will become the responsibility of the NHS Commissioning Board. The PNA may thus become a very important document – unless control of entry is abolished at a stroke!

I'd urge you to consider the following two factors:

- Are there any gaps in the service I provide to my neighbourhood – opening hours, range of services, quality of staff and premises? If there are, there is a danger that you may be faced with a speculative contract application.
- Be involved with the PNA – ensure that any shortcomings in your neighbourhood are addressed before you face the painful and time-consuming challenge of contesting a new contract application.

Elsewhere, stock shortages continue to be an issue. The excellent C+D Stock Survey 2010 clearly demonstrates that this problem is just not going away – 80 per cent of pharmacists surveyed reported that "obtaining supplies of branded medicines was more difficult than ever".

We read reports that patients in need of drugs for cancer and Parkinson's disease are subjected to even more suffering – and even cases of hospital admissions. This cannot be allowed to continue.

Pharmacists say they are not to blame, while manufacturers state that they "supply enough packs to meet the needs of UK demand". These contradictory statements cloud the issue.

The facts are simple:

- Many will argue that we accepted parallel imports – so why not parallel exports?
- AHDL devotes much time and manpower to ensure that distribution is fair – we do not want to sell less of anything.
- Pharmacos certainly do not want to sell less of their expensively researched molecules – but wish to protect their margins.
- Pharmacists battle daily to obtain medicines vital to their patients' wellbeing.
- Patients suffer.

The emergency stock summit held by the government over six months ago between pharma,

pharmacy bodies and wholesalers appears to have achieved little. The survey revealed that 86 per cent of pharmacists surveyed had seen no improvement and, further, many expected it to get worse in 2011.

So, the time has come when we as professionals need to make a stand. The interests of our patients must come first, if not we are not fit to practise. Make a noise to your MP and local press now.

The only resolution will be the introduction of legislation to outlaw exporting – it may be legal but in my view it is unethical if our patients suffer.

So power to the elbow of C+D – keep up the good work and let us know if we can change a situation that is frankly a disgrace to our profession and our industry.

"As one of those who fought for control of entry over 20 years ago, I fear that the regulations may come back and bite us on the bum"



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Unrewarded for 'touchy feely' added value



"PHARMACY IS NOT GREAT AT QUANTIFYING ITS WORTH AND IN THIS TIME OF CUTS, WE ALL KNOW IT'S NOT JUST ABOUT DISPENSING"

I had a girlfriend with expensive tastes who made me repeat the mantra that she was worth "rubies and pearls", but in reality you can't put a value on health, happiness, or friends, so how do you put a value on a profession? Pharmacy is not great at quantifying its worth and in this time of economic cuts, with everyone being asked to justify their job, we all know it's not just about dispensing – so why talk about script volume? The problem, as always, is how to count what can't be measured.

When the profits are rolling in, companies spend on 'touchy feely' things such as community projects and staff time for personal development, and when times are hard it all comes back to increased prescription targets and reduced salaries. But that's PLCs with shareholders – what about the Department of Health? How do we show that pharmacies contribute more than the advanced and enhanced services we're actually paid for.

This week I've seen some touchy feelies of pharmacy that we're not paid for, but which make a difference. Take Amber, who worked for us while at college. Perhaps not surprisingly she struggled to get a job with her Media Studies degree, but the experience and formal qualifications that we paid for mean she has secured employment – sadly elsewhere – instead of being another statistic. And what about all the informal 'social work' we do, looking out for the vulnerable and the infirm? For many patients we hold relatives' contact details,

and this week Ann has spent time reporting concerns about a vulnerable – and possibly abused – elderly person to a variety of agencies. We may not get paid directly for these actions, but they have a great deal more value than many MURs.

Of course, this was fine when, a few weeks ago, I was crowing over the silent rise of category M prices and all was right with the world. But then, lo and behold, the news is full of how it's all gone Pete Tong and the DH is raiding the Drug Tariff piggy bank again to the tune of £140 million, and the suggestion of enhanced services funded through further category M cuts – which is like saying "do extra work and pay yourselves for the privilege!"

We're told we should be grateful that 14 per cent of this smash and grab has been delayed until next year, though I'm wondering just how good a deal our negotiators have achieved when the NHS is reducing "excess GP pay" by a huge £800 or 0.75 per cent of their average salary. But I'm not bitter or jealous – no – I value myself in other ways. Let's face it – we have to!

Why is pharmacy seen as an easy target?

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Does anyone know what a PCP is?

Primary care partnerships (PCPs) are the big new idea in our reconfigured health service. If you don't know what they are then you are in good company. Ask any member of the five local commissioning groups (LCGs) what a PCP is and I suspect the answer will be so vague and confusing you'll be sorry you asked.

We know better what PCPs are not. They are not commissioning bodies; that function remains with the Health and Social Care Board (HSCB) and its five LCGs. PCPs will be provider organisations covering populations of around 100,000 people – that we know. For the Belfast LCG, the plan is to have four PCPs. They will be led by a GP and will, it is hoped, consist of a collaboration of stakeholder providers. Currently the Belfast LCG is rolling out two 'pathfinders' that will hopefully clarify what PCPs really are and what they can do.

In east Belfast a GP specialist service in ENT will hopefully reduce the numbers of patients referred to

secondary care for interventions that can easily be provided in the community – who would disagree with that? In west Belfast the pathfinder will address mental health and, having mapped out the plethora of initiatives currently funded for patients, there will be an attempt to remodel the way these services are provided. Both projects have considerable merit and potential but pinned onto both are vague commitments to addressing the prescribing overspend.

The role of community pharmacy in PCPs remains unclear, as does the role of any healthcare provider other than general practice. I suspect community pharmacists locally will be encouraged to take part and there will no doubt be a seat on the PCP board. How this will manifest in improved and properly funded service development is something very different, yet it is only this that will secure the commitment of every community pharmacy within a PCP.

2010-11 is the first time the drugs

budget, at just over £400 million, has been passed from DHSSPS to the HSCB. Judging by April to June dispensing activity, we have a potential £40m overspend for the full year. Supporting community pharmacy to address this will require something very concrete by way of a service level agreement along the lines of an enhanced service. A seat on the PCP board for one pharmacist is not going to do it. Prescribing's problem is not a lack of organisations but a lack of effective initiatives to do something rather than persuade GPs towards better practice.

The savings will come from a clear focus on three clinical treatment areas: lipids, GI and ACE inhibitors. It's that simple and it's that difficult and since, as Joe Brogan says, we won't stop prescribing and dispensing in January, February and March 2011, we will rather be forced to shut down other services. We are suddenly living in a new reality. **Terry Maguire is a community pharmacist in Northern Ireland**



"ASK ANY MEMBER OF THE FIVE LCGs WHAT A PCP IS AND I SUSPECT THE ANSWER WILL BE SO VAGUE AND CONFUSING YOU'LL BE SORRY YOU ASKED"

Update

Your weekly CPD revision guide

Multiple sclerosis: part 2

The types, effectiveness and protocols of multiple sclerosis treatments

60-second
summaryWhat is the controversy
over MS treatments?

Disease modifying drugs used in MS are expensive, and a risk-sharing scheme in which the manufacturer bears part of the cost if treatment is not cost effective has produced mixed results. While some observers argue the scheme has been a success, others have called it a waste of time and money.

What are the guidelines?

Nice has published both clinical guidelines and a specific technology appraisal relating to interferon and glatiramer acetate treatment. In addition, the Association of British Neurologists issued updated guidelines in 2009.

How effective is the new
Sativex product?

Of the 84 per cent of people with MS who have reported symptoms of spasticity, approximately 11,500 would be eligible for treatment with Sativex. Of these, estimates suggest about half will have a good response to the treatment.

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Stephen Titmarsh MRPharmS

Acute episodes of neurological symptoms may be managed with a short course of high dose steroids, but the so-called disease modifying drugs (DMDs) may be indicated for patients deemed to have certain forms of multiple sclerosis (MS), including relapsing-remitting disease.

This group of drugs has been controversial, not least because of their cost. Recently, the debate has been intensified by publication of initial results from a Department of Health-pharmaceutical industry risk-sharing scheme, and by the launch of the first of a series of a new generation of oral DMDs.

In the circumstances, patients need to be included in discussions about the management of MS and should be given an opportunity to take an active part in decisions about their treatment. They must also be given accurate information about what to expect from treatment, including the evidence that interferon beta may be only partially effective.

The Multiple Sclerosis Society (MS Society), among others, produces information for patients about symptomatic, psychological and social aspects of living with multiple sclerosis.¹

Disease modifying drugs

In 2002, a Nice technology appraisal concluded that interferon and glatiramer acetate were not cost effective.² A risk-sharing scheme was then set up in which patients who met the Association of British Neurologists' (ABN) guidelines for the use of licensed disease modifying treatments (interferon beta 1a and 1b and glatiramer acetate) in multiple sclerosis³ were given NHS-funded treatment and monitored annually for up to 10 years.

The principle of the agreement was that the effectiveness of the drug treatment would be assessed: if the treatments were found not to provide good value for money, either the pharmaceutical companies would provide financial redress or the NHS would cease funding the treatment.

Publication of initial results recently sparked debate about the merits of this kind of scheme, as well as about the treatments themselves. Some observers have argued the scheme has been a success and showed definite benefits for patients, while others have denounced it as a waste of time and NHS money.⁴

The MS Society's position is that the scheme has helped many people with MS to receive DMD treatment, and has developed a network of MS

nurses and specialist care centres. However, it also says the risk-sharing scheme has failed to recognise changes to MS professional care guidelines or to consider new evidence or drugs coming onto the market.

"The DMDs work; they reduce relapse rates and have improved quality of life for many people with MS. But the scheme has been poorly managed and it is wasting valuable time and money," the Society has argued.

In December 2009 the organisation withdrew its support for the scheme, saying it had taken the decision after repeatedly raising concerns with the DH over a four-year period to no avail. However, it had received written assurances that DMDs will still be available even if the risk-sharing scheme itself is stopped.

ABN guidelines

Revised guidelines from the ABN for the use of interferon and glatiramer acetate in multiple sclerosis were published in 2007 and revised again in 2009.³

Natalizumab and mitoxantrone received licences for the treatment of patients with rapidly evolving multiple sclerosis following the 2007 revision. The 2009 revision aimed to present a national consensus on the use of currently approved disease modifying drugs, and takes account of studies published after the earlier revision.

The 2009 guidelines concluded that in patients with relapsing-remitting multiple sclerosis (RRMS) and secondary progressive multiple sclerosis with

Complementary and
alternative medicines

Many people with MS choose to use complementary and alternative medicines (CAMs) to manage their symptoms and improve their sense of wellbeing.

Around 85 per cent of people with MS use CAMs at some stage in their disease, and half the GP practices in England provide access to CAMs in some form.

Although there is some evidence that reflexology, massage, t'ai chi, magnetic field therapy, neural therapy, fish oils and multi-modal therapy may help to improve the general sense of wellbeing of people with MS, Nice concluded there was insufficient evidence to give more firm recommendations for these treatments.⁵

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superimposed relapses, interferon beta consistently reduces relapses by about one third over two years.

This benefit may also apply to "patients with a clinically isolated syndrome in whom abnormal magnetic resonance imaging indicates a high probability of subsequent conversion to clinically definite multiple sclerosis".

The ABN guidelines say interferon beta and glatiramer acetate may also reduce the development of disability by preventing relapses that would have caused residual dysfunction, "although the effect appears modest at best, and some trials have not shown any benefit".

However, the guidelines note that interferon beta and glatiramer acetate do not seem to modify increasing disability that is not related to relapses. Whether interferon beta and glatiramer acetate improve the long-term course of the

disease, at five years for example, is not known. Specifically, it is not established that long-term interferon reduces the accumulation of disability, or prevents or slows entry to the secondary progressive stage of the disease, say the guidelines.

In clinically isolated syndromes, the ABN guidelines say interferons reduce the conversion rate to multiple sclerosis from 45 to 50 per cent in untreated patients to 28 to 35 per cent over two to three years, and glatiramer acetate probably has a similar effect. However, interferon treatment has shown only a marginally significant gain in terms of disability over three to five years, according to the guideline.

In patients with rapidly evolving aggressive relapsing-remitting multiple sclerosis, the ABN says natalizumab should be considered in accordance with Nice guidelines. In specialist centres, other treatments, including mitoxantrone, may also be considered.

Currently there are no treatments that convincingly change the course of progressive multiple sclerosis in the absence of relapses, once this stage of the disease has been reached.

As newer treatments emerge, the ABN guidelines recommend they should be offered as part of clinical trials, rather than open-label prescribing.

Both ABN and Nice⁵ guidelines advise that disease modifying treatments should be started and supervised by a consultant neurologist; preferably one with specific expertise in multiple sclerosis.^{2,3} Regular follow-up during treatment is essential to monitor and manage adverse effects, and any other problems related to the disease or its treatment.

MS specialist nurses play an important role in managing symptoms and giving information and reassurance to patients, the guidelines add.

Recent developments

Following the 2009 ABN guidelines, two new products have become available:

- the cannabinoid treatment Sativex (see the box Cannabinoid licensed for use in the UK, right)
- the oral treatment fingolimod has been launched.

Other drugs in development include another oral treatment, cladribine, and the monoclonal antibody alemtuzumab.

Steve Titmarsh MRPharmS is a former editor of the journal Progress in Neurology and Psychiatry

Download a CPD log sheet that helps you complete your CPD entry when you successfully complete the 5 Minute Test for this Update article online (p19).

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Cannabinoid licensed for use in the UK

Sativex was launched in June 2010 for the treatment of spasticity due to MS. Manufacturer GW Pharma claims it is the world's first prescription cannabis medicine, and that the UK is the first country in the world to grant a full regulatory authorisation for such a product.

Sativex is an oromucosal spray containing two cannabinoids, THC (delta-9-tetrahydrocannabinol) and CBD (cannabidiol), both of which are derived from whole plant extracts from the cannabis sativa plant.

The medicine is available only on prescription from specialist clinicians experienced in treating MS spasticity. It is sprayed into the mouth either on the inside of the cheek or under the tongue. Patients decide how many sprays they need, up to a daily limit of 12 sprays; eight sprays per day is typical.

According to the manufacturer, patient exposure to Sativex in the UK now amounts to about 1,000 patient-years.

GW Pharma says of the 84 per cent of people with MS who have reported symptoms of spasticity, approximately 11,500 would be eligible for treatment with Sativex (those who are already on combination therapy). Of these about 50 per cent will have a good response.⁶

The most common side effects of Sativex are dizziness, which occurs mainly in the first few weeks of treatment, and fatigue. GW Pharma says these reactions are usually mild to moderate and improve within a few days, even if treatment is continued.⁷

Sativex is manufactured under Home Office licence at an undisclosed location in the UK. The medicine is being marketed in the UK by GW's UK licensee, Bayer Schering Pharma.

ABN guidance for starting disease modifying treatment

Relapsing-remitting multiple sclerosis

Patients with active MS – defined by two clinically significant relapses in the previous two years – with relapsing onset can be offered treatment with interferon beta or glatiramer acetate.

Treatment may also be offered to:

- patients within 12 months of a clinically significant, clinically isolated syndrome when MRI evidence predicts a high likelihood of recurrent episodes (ie development of MS)
- patients with only a single major relapse in the preceding two years, but combined with MRI evidence of continuing disease activity (ie they meet the revised McDonald criteria for MS)
- individuals younger than 18 years old with relapsing-remitting MS.

Aggressive multiple sclerosis Patients with relapsing and remitting MS considered to be rapidly evolving and likely to become severe should be considered for treatment with natalizumab or mitoxantrone by specialist neurologists. Rapidly evolving and severe MS is defined by two or more disabling relapses in one year, with supporting MRI data.

Secondary progressive multiple sclerosis

Treatment is not recommended in non-relapsing secondary progressive MS and only in relapsing secondary progressive MS when relapses are the predominant cause of increasing disability.

Primary progressive multiple sclerosis No disease modifying treatment is indicated.

Recommendations for stopping treatment Neurologists should involve patients in decisions about starting or stopping treatment, or doing MRI scans for diagnosis and management.

The ABN says: "It is almost impossible to conclude in individual patients that treatment is providing no benefit and the problem of discontinuation is compounded by the fact that there are few alternative options for disease modification. Therefore, it is not feasible to have mandatory stopping criteria that apply in all cases."



NEXT WEEK

The first part of our series on inflammatory bowel disease

C+D Guide to Orthotics



In this C+D guide to Orthotics, you will learn:

- What excess pronation is and the problems it can cause
- Which groups or customers tend to have more sensitive feet
- How orthotics can be used to relieve many foot problems

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Walk away from pain..

- Do your customers suffer from a pain they can't explain in the heel, ankle, knee or lower back?
- Could their pain be caused by excess pronation?
- Have they got feet that are more sensitive to the effects of pressure and friction?
- Do they normally treat their pain with painkillers and rest?
- Could their pain be relieved by using orthotic inserts?



What are orthotics?

Orthotics are inserts that fit into everyday shoes and are designed to help change the position and movements of the feet. They naturally re-align the feet and ankles to correct body posture. They can be used to provide relief from many foot problems as well as knee pain, tired aching legs and for some, positive effects on lower back pain.

The foot is exposed to forces every time a step is taken. During walking the foot is the only part of the body in contact with the ground and is the first part of the body to experience the forces that are generated during walking.

Supporting the full body weight of the body and being repeatedly exposed to mechanical forces during walking, the foot has some specialised features to help it cope with these forces:

- The bone structure and movements of the foot during walking allow it to act as a very effective shock absorber when hitting the ground
- The specialised, thickened skin on the bottom of the foot is able to withstand the forces put through it
- Fat pads are found under the areas of high pressure and help cushion against some of the forces through the foot.

Although the foot is ideally designed to cope with the forces and pressures of standing and walking, it is sometimes exposed to forces that lead to the development of some common foot conditions. These conditions can develop as a result of stress or damage to the tissues or as a result of the foot trying to protect itself.

Two types of mechanical forces can be particularly problematic for the feet:

- Compressive forces known as pressure
- Shear forces known as friction
- The forces that the feet are exposed to during standing or walking impact on all of the tissues within the foot.

What is pronation?

The human foot evolved to travel on soft, natural surfaces such as soil and sand that mould to the foot. Nowadays our feet usually spend every day walking and standing on hard and flat surfaces such as pavements or floors, often in unsuitable shoes.

Pronation is the natural rolling of the foot while walking. Every time you take a step your foot hits the ground on the outside edge of the heel, and rolls over as it flattens on the ground. As it rolls, the foot turns inwards. This movement is called pronation and generates forces that the feet distribute to prevent stresses and strains. Walking on hard surfaces can lead to excess pronation, which occurs when the foot rolls inwards and the arch of the foot flattens too much. Excess pronation occurs in up to 70% of people.

In people with excess pronation, the feet are exposed to increased forces. This puts extra strain on the heels and knees and can lead to common foot problems such as flat feet, pain in the ball of foot, heel pain such as Planter Fasciitis and Achilles Tendonitis. If foot alignment is poor it may cause wear and tear to other parts of the body such as ankles, knees, hips and lower back. Ankles can become unstable, the knees bend inwards, the hips drop and the back tries to compensate, therefore straining muscles from the lower back to the shoulders and resulting in pain.



Sensitive feet

Some people have feet that are more sensitive to the effects of pressure and friction. These groups of people include:

People with diabetes

The long term effects of diabetes can lead to damage in many parts of the body, particularly the circulatory system and the nervous system. The effect of this damage on the feet can result in changes in foot shape, loss of feeling and ability to fight off infections and recover from injuries. There is a real need for people with diabetes to protect and care for their feet, minimising friction that can lead to ulcers and maintaining the foot's natural structure and position. Changes to the foot shape, reduced pain sensations and dry skin make the foot more prone to injury.

People with arthritis

Arthritis can have a major impact on the joints of the foot, resulting in pain and discomfort, and can impact on the shape and function of the foot. The changes in the shape of the joints and loss of cushioning in fat pads can lead to common foot conditions such as bunions and hammer toes and feet can be more injury prone. It is important for arthritis sufferers to protect their feet to minimise pain and discomfort.

Elderly people

The aging process can impact the overall structure and function of the feet, and can lead to dry, less elastic skin which can be less able to withstand pressure and friction.

People with minor foot trauma

Pressure and friction may increase pain and discomfort.

Walk away from pain... with Scholl Orthaheel

The Scholl Orthaheel range is unique, with different products to meet a wide range of needs. The pain each person has will be different – it could be heel pain, ball of foot pain, knee pain or even lower back pain. Some people might have problems that are not linked to excess pronation but are caused by diseases such as diabetes or arthritis. Others may have pain related to sporting activities or to wearing certain types of footwear like high heels. People will also have different needs depending on the footwear that they are wearing.



Scholl Orthaheel Regular

- Designed as a heel and ankle stabiliser
- Relieves pain associated with the heel, ankle, knee and for some people, the lower back.



Scholl Orthaheel Slimfit

- Designed for use in ladies heeled shoes to help cushion and support the feet
- Realigns the foot and relieves pain in the back of the heel and the ball of the foot
- Relieves tired aching feet and legs.



Scholl Orthaheel Gel Heel Pain Reliever

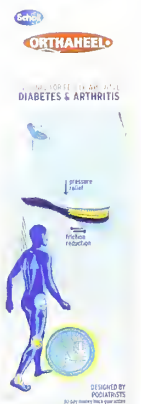
- Affects the position and motion of the foot and alters the way the forces impact during walking.
- Designed specifically to relieve pain associated with the heel.



New ...

Scholl Orthaheel Sensitive Feet

- Designed using unique Glidesoft™ technology, made up of six different layers that help protect the feet from pressure and low friction layers that help protect the feet from friction
- Useful for people who are particularly sensitive to the effects of pressure and friction on the feet, such as those with diabetes, arthritis, the elderly and those recovering from minor foot injuries
- Helps to reduce any foot movements, such as excess pronation, that may lead to pain and discomfort.



Other products available in the Scholl Orthaheel orthotics range are: **Scholl Orthaheel Workforce** – Ideal for people who are on their feet all day. **Scholl Orthaheel Sports** – Offers more 'motion control' and is ideal for running. **Scholl Orthaheel Shock Absorber** – Ideal for high impact sports.

For more information about the Scholl Orthaheel range of orthotics visit www.scholl.co.uk or call the Scholl team on 0800 074 2040



ORTHAHEEL

Multiple sclerosis: part 2

How effective is interferon beta? What treatments should be considered for patients with rapidly evolving relapsing-remitting MS? What are the side effects of Sativex?

This article discusses drug treatment for MS including the effectiveness of disease modifying drugs and who they can be prescribed for. It also includes information about Nice and Association of British Neurologists' guidelines, complementary therapies and cannabinoid treatment.

- Find out more about how DMDs work, who is eligible for them, their benefits and how they are administered from the MS Trust website at <http://tinyurl.com/msclerosis6>.
- Find out more about mitoxantrone and Sativex from the MS Trust website at <http://tinyurl.com/msclerosis7> and <http://tinyurl.com/msclerosis9>.
- Revise your knowledge of other drugs used to treat MS symptoms from the C+D MUR tips for MS at <http://tinyurl.com/msclerosis10>.
- The Multiple Sclerosis Resource Centre website at <http://tinyurl.com/msclerosis8> has information about complementary medicines and MS.
- Useful advice about managing cognitive difficulties can be found on the MS Trust website at <http://tinyurl.com/msclerosis11>.

Are you now confident in your knowledge of the disease modifying drugs that are used in the treatment of MS? Could you give advice about complementary and cannabinoid treatments to your patients?

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Step 2

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www.chemistanddruggist.co.uk/mycpd

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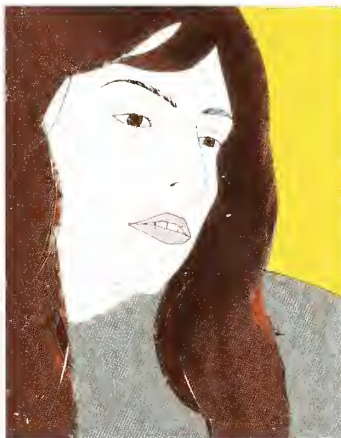
Registering for Update 2010 costs £37.60 (inc VAT) and can be done easily at www.chemistanddruggist.co.uk/update or by calling 0207 921 8425.

Signing up also ensures that C+D's weekly Update article is delivered directly to your inbox free every week with C+D's email newsletter.

Get a CPD log sheet for your portfolio when you successfully complete the 5 Minute Test online.

Practical Approach

Can you treat chronic fatigue syndrome?



At the Update Pharmacy, a woman asks to see the pharmacist. David Spencer asks how he can help.

"I've come to you as a last resort," the woman says. "I've been right through the medical system and had all the tests, but they can't seem to help me."

"So what is the problem?" asks David.

The woman replies: "I'm 24 and never had any health problems until a couple of years ago. Since then – and it's getting worse by the day – I wake up feeling so tired and washed

out that I struggle to get out of bed. I feel fatigued all day, although it's worse in the mornings. I have sore muscles and joints but there's no swelling. I have headaches everyday, and I can't seem to focus or concentrate on anything. I sometimes have dizzy spells. I just feel constantly ill. I've managed to hang on to my job, but I'm worried I won't be able to for much longer."

"You say you've been through the medical system?" says David.

"Oh yes. I've had a diagnosis but it seems there's no medicine that can cure it."

"So why have you come to me?"

"I was hoping that there's some vitamin or something herbal that might help. I'm desperate and willing to try anything that's safe."

Questions

1. What was the woman's diagnosis?
2. What pharmacological measures are used to treat symptoms?
3. Which vitamin supplements might be helpful?
4. What general advice can be given?

Answers

1. Chronic fatigue syndrome (CFS), also known as myalgic encephalitis (ME), a condition of unknown aetiology. It is diagnosed through the exclusion of other possible causes such as hypothyroidism, diabetes and anaemia as causes of fatigue, and systemic lupus erythematosus, rheumatoid arthritis and inflammatory bowel disease as causes of arthralgia.¹
2. Non-sedating antidepressants such as fluoxetine for depression; NSAIDs such as ibuprofen for myalgias and arthralgias; a low-dose tricyclic antidepressant for poor sleep or pain.

3. Vitamin B complex consists of eight vitamins – thiamine (B₁), riboflavin (B₂), niacin (B₃), pyridoxine (B₆), cobalamine (B₁₂), folic acid, pantothenic acid and biotin, plus the related substances choline, inositol and para-aminobenzoic acid (PABA). Several, including thiamine, riboflavin, niacin and pyridoxine are involved in energy production and carbohydrate metabolism. Levels of these have been found to be lower in CFS patient than in controls.² Co-enzyme

Q, a naturally occurring enzyme found in the mitochondria of body cells, which is included in some vitamin/mineral supplement products, is also important for energy production.

4. Accept the illness. Accept the equal importance of mind and body. Contact other people with CFS. Make sure family and friends understand CFS. Set priorities for improvement. Make a recovery plan. Sort out employment issues. Sort out pain control. Look at your illness beliefs and reactions. Allow time for relaxation. Maintain a positive outlook.³

References are at www.chemistanddruggist.co.uk/practicalapproach

Got an idea for a Practical Approach scenario or would you like to write one? Email your suggestion to: haveyoursay@chemistanddruggist.co.uk

For more Practical Approach scenarios, go to www.chemistanddruggist.co.uk/practicalapproach

Category M Barometer

Generic Eric reveals how October's tariff will affect your bottom line

For the first time in three quarters, the category M tariff has seen a decrease in overall reimbursement from October.

The adjustment is in the region of a £60-70 million per quarter reduction, once market growth has been factored in. This means the average pharmacy will see £2,400 removed from generics purchase profits over the coming three months.

For the third quarter in a row there has been a large amount of activity in the category, with only two out of 434 products staying at the same reimbursement level. Most savings to the NHS have been made by reducing virtually all the products in the category; of the 432 products whose reimbursement levels were changed, just nine were increased.

The most prominent reduction is on the new entrant, fenofibrate micronised 200mcg capsules, which has the most radical percentage reduction in reimbursement of 75 per cent. (The other addition to the October tariff is fenofibrate micronised 267mcg capsules, down 46 per cent.)

Next month also sees the removal from the tariff of a further 11 products, including co-amoxiclav 250/125mg and levothyroxine 25mcg.

The new basket of category M products is worth £1.3 billion, down from £1.7bn. The Category M Barometer index has decreased from 125.9 in quarter three to 102.7 in quarter four.

On the most commonly dispensed lines by volume, reimbursement prices have decreased on the majority of products in quarter four. In fact, an annualised amount of over £80m has been removed from these lines; this compares to £39m added in quarter three.

For the average pharmacy this equates to £2,000 per month being taken away from the bottom line (if whole market volumes are used and just the top 20 lines are dispensed).



Generic Eric's Factfile – the latest quarter in numbers

2,400

Pounds per quarter removed from the average pharmacy's bottom line

75

percentage drop in fenofibrate's reimbursement price

£60-70m removed this quarter

What's hot

The 10 products with the largest rise in price

	Pack size	July tariff price (£)	October tariff price (£)	Change (£)	
Gabapentin 300mg capsules	100	4.99	8.83	3.84	▲ 77%
Hydrocortisone 1 per cent ointment	15g	2.31	3.34	1.03	▲ 45%
Co-tenidone 50mg/12.5mg tablets	28	1.41	1.77	0.36	▲ 26%
Indometacin 25mg tablets	28	1.97	2.33	0.36	▲ 18%
Captopril 12.5mg tablets	56	1.38	1.51	0.13	▲ 9%
Indometacin 50mg tablets	28	2.18	2.29	0.11	▲ 5%
Metronidazole 200mg tablets	21	1.32	1.36	0.04	▲ 3%
Co-tenidone 100mg/25mg tablets	28	1.55	1.57	0.02	▲ 1%
Lormetazepam 1mg tablets	30	54.26	54.60	0.34	▲ 1%
Flucloxacillin 125mg/5ml oral solution	100ml	4.41	4.41	0.00	▲ 0%

What's not

The 10 products with the largest fall in price

	Pack size	July tariff price (£)	October tariff price (£)	Change (£)	
Fenofibrate micronised 200mg capsules	28	14.23	3.53	10.70	▼ 75%
Aspirin 300mg dispersible tablets	100	5.76	2.88	2.88	▼ 50%
Fenofibrate micronised 267mg capsules	28	21.75	11.69	10.06	▼ 46%
Meloxicam 15mg tablets	30	2.94	1.62	1.32	▼ 45%
Senna 7.5mg tablets	60	2.57	1.47	1.10	▼ 43%
Losartan 25mg tablets	28	4.53	2.64	1.89	▼ 42%
Losartan 100mg/hydrochlorothiazide 25mg tablets	28	7.22	4.37	2.85	▼ 39%
Losartan 100mg tablets	28	4.64	2.84	1.80	▼ 39%
Sulfasalazine 500mg gastro-resistant tablets	100	26.61	16.39	10.22	▼ 38%
Bisoprolol 2.5mg tablets	28	4.32	2.67	1.65	▼ 38%

Data and analysis supplied by Actavis

CPD Reflect • Plan • Act • Evaluate

Tips for your CPD entry on Cat M

REFLECT	Do I understand how category M affects my pharmacy?
PLAN	Read this article to learn about the latest changes
ACT	Change purchasing habits to protect profits
EVALUATE	Is my pharmacy better able to cope with Cat M fluctuations?

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Abbreviated Prescribing Information: Sumatriptan 6 mg/0.5 ml Solution for Injection

Name of the medicinal product: Sumatriptan 6 mg/0.5 ml Solution for Injection **Qualitative and quantitative composition:** Each pre-filled pen contains 6 mg of Sumatriptan, as sumatriptan succinate. Excipient: Sodium 1.3 mg. **Therapeutic indications:** Subcutaneous injection of Sumatriptan is indicated for the acute relief of migraine attacks, with or without aura, and for the acute treatment of cluster headache. Sumatriptan should only be used where there is a clear diagnosis of migraine or cluster headache. **Dosage and method of administration:** Sumatriptan should be injected subcutaneously using a pre-filled pen. **Children and Adolescents under 18 years of age:** Not recommended. **Elderly (over 65):** Not recommended. **Contraindications:** Hypersensitivity to sumatriptan or to any of the excipients. Sumatriptan should not be given to patients who have had heart disease or in patients with hypertension. The concomitant administration of ergotamine or derivatives of ergotamine is contraindicated. Concurrent administration of monoamine oxidase inhibitors and Sumatriptan is contraindicated. Sumatriptan must not be used within two weeks of discontinuation of therapy with monoamine oxidase inhibitors. **Special warnings and precautions for use:** Warnings: Sumatriptan is not indicated for use in the management of hemiplegic, basilar or ophthalmoplegic migraine. The recommended doses of Sumatriptan should not be exceeded and should not be given intravenously, as it can cause vasospasm. Before treating headaches in patients not previously diagnosed as migraineurs, and in migraineurs who present with atypical symptoms, care should be taken to exclude other potentially serious neurological conditions. Migraineurs may be at risk of certain cerebrovascular events. If concomitant treatment with Sumatriptan and an SSRI/SNRI is clinically warranted, observation of the patient is advised. Sumatriptan should be administered with caution to patients with conditions which may affect the absorption, metabolism or excretion of the drug. Sumatriptan should be used with caution in patients with a history of seizures or other risk factors which lower the seizure threshold, as seizures have been reported in association with Sumatriptan. Patients with known hypersensitivity to sulphonamides may exhibit an allergic reaction following administration of Sumatriptan. Reactions may range from cutaneous hypersensitivity to anaphylaxis. **Undesirable effects:** Some of the symptoms reported as undesirable effects may be associated with symptoms of migraine, immune system disorders, hypersensitivity reactions ranging from cutaneous hypersensitivity (such as urticaria) to anaphylaxis, nervous system disorders, eye disorders, cardiac disorders, anxiety, vascular disorders, respiratory, thoracic and mediastinal disorders, musculoskeletal and connective tissue disorders, general disorders and administration site reactions, minor disturbances in liver function tests have occasionally been observed. **Legal Category:** POM. **Marketing Authorisation Holder:** Sun Pharmaceuticals Europe B.V. Polansavenue 87, 2132 JH Hoofddorp, The Netherlands. **Marketing Authorisation Number:** PL 31750/0012 **Pack size and cost:** Each carton contains 2 pre-filled pens. £39.50. **Further information available on request from:** Sun Pharmaceuticals UK Limited, 1200 Century Way, Thorpe Park, Colton, Leeds, LS15 8ZA UK. **Date of Preparation:** July 2010.

ETHICAL DILEMMA

This series aims to help you make the right decisions when confronted by an ethical dilemma. Every month we present a scenario likely to arise in a community pharmacy and ask a practising pharmacist and/or a member of the Pharmacy Law and Ethics Association (PLEA) to comment on the legal and ethical implications of the actions open to you. Readers are invited to have their say at haveyoursay@chemistanddruggist.co.uk

Dealing with patient prescribing requests



The dilemma

You are a pharmacist prescriber who runs a clinic for a local surgery, specialising in respiratory medicine. You carry out an annual review of a patient's condition and you have access to their medical notes so are aware of their co-morbidities and regular repeat medication. At the end of a consultation, as you are busy writing out the relevant prescription, the patient asks, "While I'm here, could you just prescribe me some of my water tablets?" The patient has been on furosemide 40mg OD for several months. What do you do?

The RPSGB advises that all pharmacist prescribers, whether supplementary or independent, must prescribe within their competencies and only medication appropriate for the patient. You know the patient is already being prescribed the requested item by a GP, but it is for a condition you do not normally deal with.

Patients can put pressure on pharmacists and it would be easy to cave in. However, it is your signature on the prescription and you would be held to be legally responsible if anything were to go wrong – even if the item is normally prescribed by a GP. It would be difficult to defend your actions in a court of law if you could not demonstrate your expertise in a particular area.

In Scotland, pharmacists are able to prescribe on a community pharmacy urgent supply (CPUS) prescription any repeat medication that a patient gets for their usual quantity (generally up to two to three months), as long as the patient is registered with a Scottish GP. If the patient is from elsewhere in the UK, pharmacists have to make an

emergency supply, as in England and Wales, and can only give up to 30 days plus levy a charge for the medication.

If the patient asks for something that I would normally be comfortable selling to them over the counter, such as emollients, antihistamines, or laxatives, I would not have a problem issuing them with their normal prescription. However, if they were asking for their usual medication for a more serious condition, such as heart failure or epilepsy, I would have to refuse as I do not have expertise in those areas.

Valerie Sillito is an independent prescriber working in the community for Alliance Boots in Aberdeen

What the law says

The July 2010 edition of the Society's Medicines, Ethics and Practice (which will be replaced by a new code on September 27 when the General Pharmaceutical Council [GPhC] takes over pharmacist regulation) provides that "Pharmacist independent prescribers can prescribe any medicine (licensed or unlicensed) with the exception of controlled drugs for any clinical condition, but they must only prescribe within their professional and clinical competence", and it is difficult to imagine that the GPhC will adopt a different approach.

Since a breach of the code of ethics may be evidence of misconduct, any pharmacist prescribing that falls outside of the pharmacist's "professional and clinical competence" could lead to an investigation by the GPhC.

There could be other consequences of prescribing errors. For example, if a patient falls ill as a result of a prescription written by a

pharmacist then, like a doctor, that pharmacist could be the subject of a claim for damages. If a patient were to die as a result of a prescription written by a pharmacist, that pharmacist could be investigated by the police for manslaughter.

In conclusion, given the consequences of an error, care should always be taken when prescribing. The pharmacist in this scenario (who refused to prescribe the item despite pressure from the patient) is adopting the wisest course of action.

Noel Wardle is a solicitor at Charles Russell LLP, specialists in pharmacy law

More dilemmas are online at www.chemistanddruggist.co.uk/ethicaldilemma

PLEA

PLEA is an association of pharmacists interested in law and ethics, and lawyers or ethicists specialising in pharmacy, with the aim of promoting understanding of the ethical basis for professional judgement
www.wingfieldworks.co.uk/plea/index.html

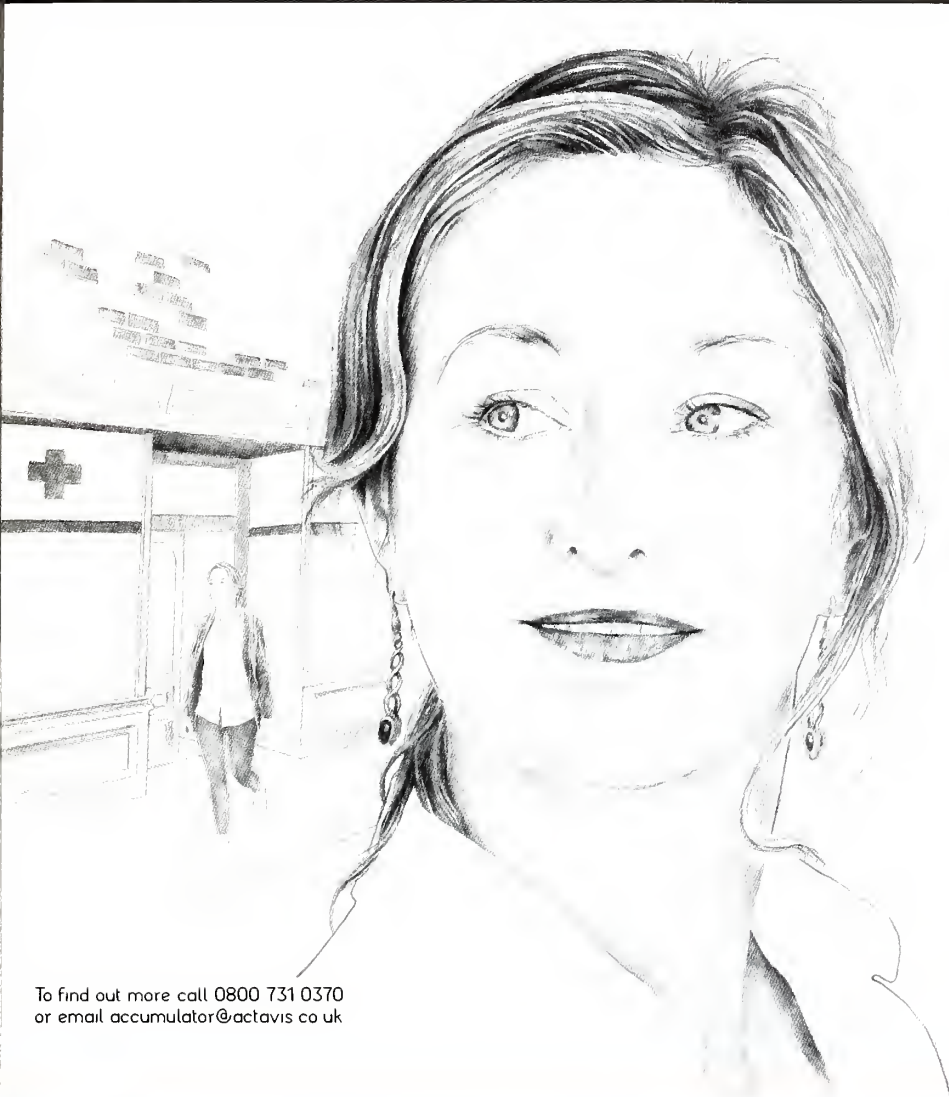


CPD Reflect • Plan • Act • Evaluate

Tips for your CPD entry on prescribing ethics

REFLECT	What are your areas of clinical competence when prescribing?
PLAN	Consider what you would do if a patient asks you to prescribe
ACT	Roleplay the consultation with a colleague to practise your skills
EVALUATE	Are you confident in refusing a request to prescribe?

We need more Ethical Dilemmas. If you have an interesting scenario that you can share with your fellow pharmacists, get in touch via haveyoursay@chemistanddruggist.co.uk



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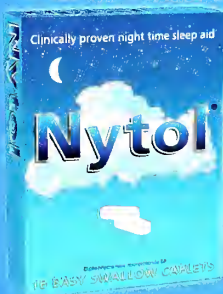
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¹. ACN, total sleeping aids, value sales, MAT to w/e 12.06.10

Nytol and **Nytol One-A-Night** are aids for the relief of temporary sleep disturbance. **Nytol Herbal Tablets** are to soothe and so aid restful sleep. **Legal categories:** Nytol Herbal GSL, Nytol and Nytol One-A-Night P. **Further information is available from:** GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K.

Nytol, **Nytol One-A-Night** and **Good Mornings Follow a Good Nytol** are registered trade marks of the GlaxoSmithKline group of companies.

CATEGORY FOCUS

Skincare

From suncare to eczema, the skincare market is worth £2bn in the UK. **Hannah Flynn** looks at how pharmacists can boost their share of this diverse sector

The skincare market, including suncare, was estimated to be worth £2 billion in the UK in 2009, according to market analyst Key Note. This represents a year-on-year rise of 5 per cent, and skincare makes up over a quarter of total value sales of toiletries in the UK.

It is a diverse market, but there are several distinct areas in which pharmacists can focus their efforts to ensure customers are getting the most out of their products, and boost their own sales in the process.

Eczema and dermatitis

Pharmacy's share (excluding Boots and Superdrug) in the eczema and dermatitis market decreased in 2009, according to data analyst

Four tips to boost your skincare sales

1 "Take just one line which includes face and body products and sell it as a whole system so the products become a skincare system rather than individual products."

Lawrence Boone, managing director, Pasante Healthcare

2 "People with chronic conditions react differently to different products and should be offered help to find what works for them. We offer 30g samples so patients can try our products first; pharmacists should suggest this to patients."

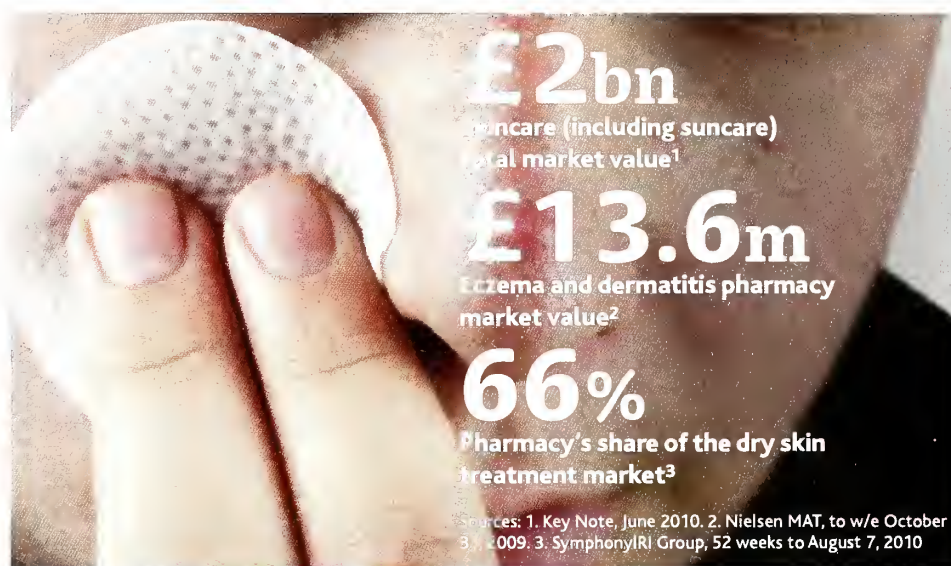
Janet McClean, marketing manager, Derma division, Thornton & Ross

3 "Pharmacists need to ask patients about previous treatments to help identify where treatment went wrong and where it can be improved."

Aini Alcock, lead clinical pharmacist, Sheffield Teaching Hospitals Foundation Trust

4 "Skincare is very experimental and pharmacists need to help keep their patient's spirits up while they try to find the products that work for them."

Ann Hart, pharmacist, Lloydspharmacy, Selfridges



Nielsen. It is currently worth £13.6 million, representing a decline of 8.5 per cent, year-on-year. The total market is worth £40.9m, and has experienced a slower decline of 2.5 per cent over the past year.

Despite this, the past year has seen launches in this subcategory of the skincare market. Thornton & Ross this month announced the launch of a Derma division, which will focus on the prescription emollient sector. According to data from analyst IMS, this sector is worth £120m and is experiencing 8 per cent year-on-year growth.

Janet McClean, marketing manager of the new Derma division at Thornton & Ross, says this sector is stable as it treats a chronic condition.

Ms McClean explains: "I think the market is going to grow as eczema affects one in five children and one in five adults. The population is increasing and things like allergens and other environmental triggers can affect it."

Rates of eczema have increased over the past 10 years, adds Pasante Healthcare managing director Lawrence Boon, which distributes sensitive skincare product range Sebamed. He says there was a 42 per cent rise in the number of eczema cases diagnosed between 2001 and 2005, and also cites a 40 per cent rise in sales of the Sebamed range over the past year.

Mr Boon says: "Customer understanding of science has increased and they are asking for more from their products and want to know what it contains besides vanilla essence."

Market changes 2009-10 Medicated skincare

Total market value **10.3%**
£76,127,600

Pharmacy** **24.4%**
£3,738,737

Grocery* **9.1%**
£71,407,080

Dry skin treatment

Total market value **1.9%**
£73,710,304

Pharmacy* **0.8%**
£48,883,536

Grocery** **8.7%**
£23,499,328

*includes Boots and Superdrug

**excludes Boots and Superdrug

Source: SymphonyIRI Group,
52 weeks to August 7, 2010

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H E A L T H Y S K I N F E E L S G R E A T

Prescribing information E45 Itch Relief Cream. E45 Itch Relief Cream contains lauromacrogols 3.0% w/w and urea 5.0% w/w. Uses: For treatment of pruritus, eczema, dermatitis and scaling skin conditions where an antipruritic and/or hydrating effect is required. It may also be used for the continued treatment and follow-up treatment of these skin diseases. Dosage and administration: Adults, the elderly and children: Apply to each affected area twice a day. The duration of treatment depends on the clinical response.

Contraindications: Patients with known hypersensitivity to any of the ingredients. It should not be used to treat acute erythroderma, acute inflammatory, oozing or infected skin lesions. **Special warnings and precautions for use:** May cause irritation if applied to broken or inflamed skin. **Pregnancy and lactation:** There are no specific restrictions concerning its use during pregnancy, but it is not to be used on the breasts immediately prior to breast feeding during lactation. **Undesirable effects:** E45 Itch Relief Cream has

been reported to cause a burning sensation, erythema, pruritus or the formation of pustules. Contact allergy has also been reported. **Packaged quantities:** 50g and 100g tubes, 500g pump pack. **RRP excluding VAT:** 50g £2.54, 100g £3.11, 500g £14.99. **Legal category:** GSL. **Product licence number:** PL 00327/0122. **Product licence holder:** Crookes Healthcare Ltd, Nottingham NG2 3AA. Further information is available from: Reckitt Benckiser UK Healthcare, Dansom Lane, Hull HU8 7DS.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to the Medical Information Unit, Reckitt Benckiser, Hull (0500 455 456).

Reference: 1. Vieluf D et al. *Z Hautkr* (1992) 67:9:816-821.

Date of preparation: May 2010.

E45HCE201005

Acne and medicated skincare

The medicated skin care subcategory is worth £76m, according to market analyst SymphonyIRI Group, which represents an 10 per cent decline year-on-year. However, acne is a condition that was highlighted in the PAGB's annual report as a minor ailment that could be treated with OTC medication. Though there is an overall downward trend in this area, the medicated skin treatment format – which represents almost a fifth of the subcategory – has grown by 9 per cent over the past year, according to IRI. Cleansers, which make up a further fifth of the subcategory, are also showing growth – of 4 per cent.

Anti-ageing and cosmetic skincare

Growth in the skincare market continues to be driven by premium-priced anti-ageing formulations, according to a Key Note report.

One notable event in the area this year was the repackaging of Astral, a heritage product that is currently the focus of a £500,000 campaign citing the benefits the product offers to ageing skin. This followed clinical research into the effects the cream has on skin on women over 50.

Camouflage products are also becoming increasingly popular. Lloydspharmacy offers a Dermablend service at its London Selfridges store (see case study, below) and Varama Covercream is currently going through approvals to be made available on prescription, according to Vanessa Jane Davies, the creator of the product. She says GPs generally direct patients to occupational therapists, who offer skin camouflage services in hospital, but thinks making the product available on prescription as well will help customers considerably.

Case study



LLOYDSPHARMACY, SELFRIDGES, LONDON ANN HART

The Lloydspharmacy branch in the Selfridges department store on London's Oxford Street has offered patients a Vichy Dermablend service for the past five months.

The free service, which offers skin camouflage for facial imperfections or scarring, is used by patients with many different conditions, according to pharmacist Ann Hart.

Ms Hart says patients come to use the service for a number of reasons. Some want to cover up a tattoo for a wedding, or cover up veins in their legs for a holiday, while some people come frequently for help covering birthmarks and rosacea.

Ms Hart says: "I think it is a good service to offer patients, as they need it. The product is available on prescription and over the counter, and people get referred here by their GPs."

All of the staff in the pharmacy are trained to offer the service, so there is always a member of staff present if it is requested.

The fact that Vichy Dermablend is a pharmacy-only product helps emphasise the importance of the product and the service, says Ms Hart.

She says: "Skin services are very much a question of training and knowledge. We have all been trained in how to use Dermablend, and it is important we keep abreast of other products we sell as the knowledge needed changes all the time."

CPD Reflect • Plan • Act • Evaluate

Tips for your CPD entry on skincare

- REFLECT** Are my patients getting the most out of skincare products?
- PLAN** Review my and my staff's knowledge and sales protocols.
- ACT** Read this article, revise common skin conditions such as eczema and acne, review available products and arrange training as necessary.
- EVALUATE** Do my patients get better advice on managing skin conditions?

Product Watch

Aquamol

Manufacturer: Thornton & Ross

Classification: GSL

For: Managing mild to moderate eczema, psoriasis and other dry skin conditions

Active ingredients: Aquamol is an emulsion of oil in water containing penetration enhancers

What's new? This product has just been launched by T&R Derma, a recently launched division of the company focusing on the prescription emollient market

www.trderma.co.uk

Tel: 01484 842217



Format/pack size: 50g; 500g

Pip codes: 356-4135; 356-4143

RRP: £1.22, £6.40

Frederm Deep Pore Cleansing Wipes

Manufacturer: Dendron

Classification: Cosmetic

For: Preventing spots

Active ingredients: Deep-cleansing anti-bacterial action

What's new: Frederm Deep Pore Cleansing Wipes launched last month

www.frederm.co.uk



Format/pack size: 25

Pip code: 356-7666

RRP: £3.99

Exorex Lotion

Manufacturer: Forest Laboratories UK

Classification: GSL

For: Treating mild to moderate psoriasis

Active ingredient: Coal tar extract

www.exorex.co.uk

Tel: 0 1322 421800



Format/pack size: 100g; 250g

Pip codes: 242-2125; 242-2133

RRP: £14.95; £29.95

Eumovate Eczema and Dermatitis Cream

Manufacturer: GSK Consumer Healthcare

Classification: P

For: Short-term treatment and control of localised patches of eczema and dermatitis, including atopic eczema and primary irritant and allergic dermatitis

Active ingredients:

Clobetasone butyrate 0.05 per cent

USP: Eumovate Eczema and Dermatitis Cream can clear skin flare-up in as little as five days and relieve itch, breaking the itch-scratch cycle in as little as three days, the manufacturer claims

www.mypharmassist.co.uk

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Pip code: 281-9142

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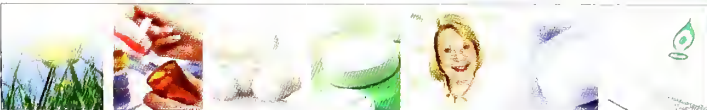
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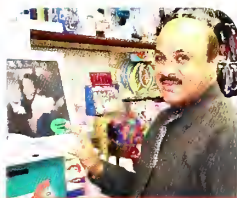
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Postscript...

Under pressure

A pharmacy in Wimbledon has asked local residents if they are gambling with their health by not getting their blood pressure checked.

Mount Elgon Pharmacy in Wimbledon Chase will be offering free checks to patients wanting to find out what their blood pressure is, alongside the Blood Pressure Association's Know your Numbers! campaign.

Mike Rich, executive director of the Blood Pressure Association, said: "We are delighted Mount Elgon Pharmacy is taking part in Know your Numbers! Week 2010, highlighting the importance of knowing your blood pressure."



"During this year's campaign, we're asking 'Are you gambling with your health?' and we hope everyone will take advantage of the free blood pressure checks to lower their odds of stroke and heart attack."

A social tweet

From newbies to EPS claims, join the debate at www.twitter.com/chemistdruggist



@GaryParagpuri: We have an interview with new RPSGB chief Helen Gordon next week. What do you want to ask her? And do you want to be part of the interview?

@jonathanmason: This is my first Tweet – hi everyone, I will be using Twitter to get ideas for my weekly C&D video blogs, & to hear what you think about...

@CandZoe: Catching up with CfH and I see they say the electronic prescriptions service has been delivered... seems quite a bold statement.



C+D reader of the week

Meet Buttercups Training managing director Vanessa Kingsbury, who would love to join a certain Time Lord on his travels

What is the craziest thing you have ever done? Thinking I could row a dragon boat, even considering my lack of fitness. (Vanessa recently participated in Nottingham Riverside Festival Dragon Boat Challenge to raise money for Rainbow Hospice for Children and Young People in Loughborough.)

What is the best thing about C+D? I like the comment by the editor as it is a quick insight into current affairs in the pharmacy community.

What is your secret talent? I don't share secrets.

What is the strangest request you have ever received? Do you sell lemons, was a good one. I also got asked if I could help a man tie his bow tie as he was going to a wedding and couldn't tie it. I never knew if he managed it or not.

If you could have a superpower, what would it be? I would like to be able to time travel as I am a Doctor Who fan and I would like to be his assistant.

What is your favourite book? 100 Years of Solitude by Gabriel García Márquez. That's because it is utterly absorbing and intense and I needed to read it twice.

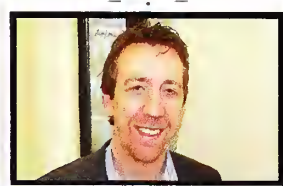
What would you do if I gave you £1,000? I would give it to the Rainbow Hospice as it's a hospice for terminally ill children.

What would you be if you were not a pharmacist? I would be a novelist.

What is the best idea you have ever had? To open a coffee shop in my husband's pharmacy, but he dismissed the idea out of hand.

What question should we ask our next reader of the week? What great wrong would you right?

Calling all pharmacists and technicians. We want you to be our reader of the week. Email us at postscript@chemistanddruggist.co.uk



@The Web Hunter

How often do you hear someone talk about the inevitability of change? And often it is associated with new government, new ways of working or with technology.

The internet is a technology that has forced change into many aspects of life, from TV, shopping and banking to how we socialise, educate and listen to music. And pharmacy is not immune. The backbone of the web, internet protocol or IP, has allowed us to do things remotely without the need for shifting millions of pieces of paper around.

Now on the surface EPS is an example of another logical step down the paperless route. And to a technophile like myself there is little wrong with the idea of replacing paper-based prescriptions with electronic paperless ones.

For the patient, they don't have to worry about losing it on the way to the pharmacy (something I have done recently). And on the surface it allows pharmacists to be better organised, because they should (in theory at least) be able to better manage workloads.

And in the case of repeat prescriptions against a dark background of worsening supply and inevitable stock shortages, it could potentially allow a pharmacist to pre-order the harder-to-find drugs ahead of a pensioner rocking up expecting everything on the script right here, right now.

So on the surface it's all good. But let's think about another saying: if it ain't broke don't fix it. People have been carrying little bits of green paper from the GP to the pharmacist for years. It's a system that surely could be improved by electronic transmission of prescription data, but works for GP, pharmacist and patient.

The NHS Prescription Services agency, which has to pay people to handle the millions of scripts dispensed by pharmacy, will certainly make a saving (and probably put a few people out of work). But GP, pharmacist and patient be warned, this could just be change for change's sake.

Niall Hunt is C+D's digital content editor; email him at niall.hunt@ubm.com

Last week's top stories on C+D's website

1. Lloydspharmacy and Co-operative to review spending ahead of Cat M raids
2. GPhC agrees 2011 fees and direct debit charges
3. Government stockpiles medicines to prevent shortages
4. Dorothy Drury quits RPSGB Council over lack of results

The C+D Conference

at the Pharmacy Show

NEC Birmingham 10-11 October 2010

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for details

Sunday, October 10

12.30pm

The five biggest challenges facing pharmacy and what the Society will do to help you

Helen Gordon, chief executive, the RPS

As the RPSGB returns to its roots as the leadership body for pharmacists, its new chief executive reveals how the Society will steer pharmacists to a more rewarding professional future

1.10pm

How your life will change under the new pharmacy regulator

Duncan Rudkin, chief executive, General Pharmaceutical Council

Pharmacists have a new professional regulator but will it just lead to tougher sanctions or will the promise of 'light touch' regulation become a reality? The GPhC's Duncan Rudkin reveals what the profession's new disciplinarian will mean for you

1.50pm

The inside track on stat comms and what pharmacists have to do to ensure they get a fair hearing

David Reissner, head of healthcare, Charles Russell solicitors

With community pharmacy now facing more scrutiny than ever before, David Reissner looks at what you should do if you're investigated and the sanctions you could face from the GPhC and PCTs

2.30pm

Pharmacy contract funding – a behind-the-scenes account of where we are and what the future holds

Sue Sharpe, chief executive, PSNC

PSNC chief executive Sue Sharpe explains what's happening in the latest round of contract funding negotiations and what the future NHS Commissioning Body will mean for your funding

3.15pm



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C+D's pharmacy think-tank holds its first ever live event. An expert panel will discuss the big issues impacting on grassroots pharmacy practice and will field questions from the audience.

Don't miss this unique chance to be part of the debate. Panellists include Ian Facer, NPA; Rob Darracott, CCA; Sue Sharpe; Michael Cann; David Reissner; RPS English Pharmacy Board chair Lindsey Gilpin; and Jonathan Mason, national clinical director for pharmacy, Department of Health.

**Every session will include an audience Q+A
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Monday, October 11

10.20am

The new white paper – where next for NHS services?

Alan Milburn, former secretary of state for health.

The government's vision for primary care will see GPs charged with commissioning local services as PCTs are consigned to the scrap heap. Alan Milburn examines whether the new NHS blueprint will change the NHS landscape for better or for worse

11.00am

A multiple's view of the new look NHS

Andy Murdock, director of pharmacy, Lloydspharmacy

Following the white paper theme, Lloydspharmacy's Andy Murdock identifies the opportunities and threats that pharmacy faces under the latest NHS revolution

11.40am

What the new dawn in pharmaceutical wholesaling means at the coal face

Mark James, managing director, AAH

Quotas, DTP, discounts and parallel trading – the supply chain is the one topic that affects every pharmacist. Mark James cuts through the crossfire and looks for a workable solution

12.20pm

Generics, the NHS, and you

Michael Cann, chairman, BGMA

Love 'em or hate 'em, generics play a major part in keeping the NHS drugs bill down. Michael Cann looks at the opportunities that generics provide for pharmacists including category M and generic substitution

1.00pm

How ditching toiletries and cosmetics helped boost our healthcare business

Kenny Black, managing director, Rowlands Pharmacy

Rowlands Pharmacy has piloted a new front of shop business model which has seen toiletries and cosmetics replaced with a greater focus on healthcare. Kenny Black explains why pharmacy must change and shares top tips from the Rowlands experience

1.40pm

Where next for commissioning – what's important for pharmacy?

Julie Wood, director, clinical commissioning, NHS Alliance

There's no escaping the 'c' word – it's a fact that commissioning is going to be a big part of pharmacy's future. Julie Wood offers her views on what's important for pharmacy as commissioners and as providers of services

2.20pm

An examination of Co-op's blueprint for pharmacy

Chris Brooker, business development director, The Co-op Pharmacy

The Co-operative Pharmacy is one of the fastest growing multiple chains. Chris Brooker shares the company's blueprint for pharmacy and offers his tips on maximising your business

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NiQuitin Mints Mint 4mg/4mg Lozenges (nicotine). Indications: smoking cessation. **Dosage: Adults (18 and over):** One lozenge (max. 15/day) whenever urge to smoke to aid complete cessation (taper use after 6 weeks) or gradual cessation (seek advice if no reduction after 6 weeks) or gradual cessation (seek advice if no reduction after 6 weeks or no abrupt attempt after 6 months); professional advice if use >9 months. Use 1.5mg strength if smoke <20/day, otherwise 4mg. **Adolescents (12-17 years):** Abrupt cessation only. Dosing as for adults but seek professional advice if >12 weeks treatment required/unable to quit abruptly. **Contraindications:** Hypersensitivity, non-smokers, children under 12 years. **Precautions:** Risk of NRT substantially outweighed by risks of continued smoking in virtually all circumstances. Supervise use in those hospitalised for MI, severe dysrhythmia or CVA who are haemodynamically unstable. Once discharged, can use NiQuitin as normal. Susceptibility to angioedema, urticaria. Renal/hepatic impairment, hyperthyroidism, diabetes, pheochromocytoma. Swallowed nicotine may exacerbate oesophagitis, gastric/peptic ulcer. **Pregnancy/lactation:** For those unable to quit, unaided the risk of continued smoking is greater than the risk of using NRT. Start treatment as early as possible in pregnancy for 2-3 months. Lozenge/gum preferable to patches unless nauseous. **Side effects:** At recommended doses, NiQuitin Mints have not been found to cause any serious adverse effects. In use: hiccup, flatulence,

GI discomfort, vomiting, diarrhoea, dyspepsia, fatigue, malaise, chest pain, oral irritation, dizziness, headache, sleep disorders including abnormal dreams, anxiety, irritability, nervousness, depression, palpitations, increased heart rate, cough, sore throat, rash, anaphylaxis. See SPC for full details. **GS1 PL 00079/0610, 0611. PL holder:** GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K. **Pack sizes and RSP (excl. VAT):** 20's £4.75, 60's £13.32. **Date of revision:** August 2009.

NiQuitin 21, 14, 7mg Transdermal Patches, NiQuitin Clear 21, 14, 7mg (nicotine). Opaque or transparent transdermal patches 21mg, 14mg, 7mg nicotine (Steps 1, 2, 3) for relief of nicotine withdrawal symptoms during smoking cessation. **Dosage: Adults (18 and over):** >10 cigarettes/day: Step 1 for 6 weeks, then Step 2 for 2 weeks, then Step 3 for 2 weeks. <10 cigarettes/day: Step 2 for 6 weeks then Step 3 for 2 weeks. Apply to fresh site (clean, dry skin) once daily. Professional advice if use >9 months. **Adolescents (12-17 years):** As for adults but to seek professional advice if >12 weeks treatment required. **Contraindications:** Hypersensitivity, occasional/non-smokers, children under 12 years. **Precautions:** Risk of NRT substantially outweighed by risks of continued smoking in virtually all circumstances. Supervise use in those hospitalised for MI, severe dysrhythmia or CVA who are haemodynamically unstable. Once discharged, can use NiQuitin as normal. Susceptibility to angioedema, urticaria. Discontinue use if severe/persistent

skin reactions. Renal/hepatic impairment, hyperthyroidism, diabetes, pheochromocytoma. **Pregnancy/lactation:** For those unable to quit, unaided the risk of continued smoking is greater than the risk of using NRT. Start treatment as early as possible in pregnancy for 2-3 months. Lozenge/gum preferable to patches unless nauseous. Remove patches at bedtime. **Side effects:** At recommended doses, NiQuitin patches have not been found to cause any serious adverse effects. Local rash, itching, burning, tingling, numbness, swelling, pain, urticaria, heaviness, hypersensitivity reactions. Headache, dizziness, tremor, sleep disorders, nervousness, palpitations, tachycardia, dyspnoea, pharyngitis, cough, GI disturbance, sweating, arthralgia, myalgia, malaise, anaphylaxis. See SPC for full details. **GS1 PL 00079/0368, 0367, 0366, 0356, 0355 & 0354. PL holder:** GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K. **Pack sizes and RSP (excl. VAT):** 7 patches £14.89; Step 1 only 14 patches £28.04. **Date of revision:** August 2009. **NiQuitin[®], NiQuitin[®] Minis** and the **Minis Device** are trademarks of the GlaxoSmithKline group of companies.

Reference: 1. National Institute Clinical Excellence. Smoking cessation services in primary care, pharmacies, local authorities, and work places, particularly for manual working groups, pregnant women and hard to reach communities. Public Health Guidance 10. February 2008.



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